

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

THERASENSE, INC.,
Plaintiff,

v.

BECTON, DICKINSON AND COMPANY,
Defendant.

No. C04-02123 MJJ
No. C04-03327 MJJ
No. C04-03732 MJJ
No. C05-03117 MJJ

**ORDER RE: DEFENDANTS'
NONINFRINGEMENT AND
INVALIDITY SUMMARY JUDGMENT
MOTIONS**

INTRODUCTION

Before the Court are five summary judgment motions brought by the Defendants (Bayer, Roche, and BD/Nova) in these related patent infringement actions. The motions include three non-infringement motions:

- (1) a motion for summary judgment of noninfringement brought by Bayer with respect to the '551 patent;
- (2) a motion for partial summary judgment of noninfringement brought by Roche with respect to the '745 patent; and
- (3) a motion for summary judgment of noninfringement brought by BD/Nova with respect to the '164, '551, and '745 patents.

The other two motions address invalidity issues. They are:

- (4) a motion for summary judgment of invalidity brought by BD/Nova with respect to the '890 patent; and
- (5) a motion for summary judgment of invalidity brought by all Defendants with respect to the '745 patent.¹

Plaintiff Abbott opposes all of the relief sought by these motions. The motions have been fully briefed by the parties, and have been the subject of extensive oral argument.²

Having carefully considered the evidence and argument submitted by the parties,³ the Court rules as set forth below.

FACTUAL BACKGROUND

The four related lawsuits that gave rise to the summary judgment motions before the Court concern four United States patents owned by Abbott Diabetes Care Inc. and Abbott Laboratories (collectively "Abbott"): U.S. Patent Nos. 5,628,890, 5,820,551, 6,143,164, and 6,592,745. In the lawsuits, Abbott has asserted that blood-glucose test strips marketed and manufactured by the Defendants infringe one or more of the Abbott patents.

In Case Nos. 04-2123, 04-3327, and 04-3732, Abbott contends that Defendants Becton, Dickinson and Co. ("BD") and Nova Biomedical Corporation ("Nova") (collectively "BD/Nova") wilfully infringe the four Abbott patents-in-suit, entitling Abbott to damages and injunctive relief. BD/Nova alleges it does not infringe the Abbott patents and that the Abbott patents are invalid, thereby entitling BD/Nova to declaratory judgments of non-infringement and patent invalidity.

¹ Defendants Roche and Bayer filed this motion. BD/Nova has filed a joinder.

² In advance of the hearing, the Court provided a written list of questions to the parties. All of these questions were addressed by the parties during oral argument.

³ Good cause appearing therefor, the Court **GRANTS** four motions filed by Abbott to supplement the summary judgment record after briefing was completed. These are: (1) Abbott's January 15, 2008 motion for leave to file additional exhibits in response to new arguments asserted by Defendants on their reply brief regarding invalidity of the '745 patent; (2) Abbott's February 15, 2008 motion for leave to file a sur-reply and additional new evidence in support of its opposition to Roche's noninfringement motion regarding the '745 patent; (3) Abbott's February 15, 2008 motion for leave to file additional new evidence in support of its opposition to Defendants' motion for summary judgment of invalidity regarding the '745 patent; and (4) Abbott's February 20, 2008 motion for leave to file supplemental evidence in support of its opposition to Bayer's and BD/Nova's noninfringement motions regarding the '551 patent. The Court has considered this supplemental evidence as part of the summary judgment record, as well as Defendants' responses and objections thereto.

In Case No. 05-3117, Abbott contends that Defendants Roche Diagnostics Corporation (“Roche”) and Bayer Healthcare LLC (“Bayer”) wilfully infringe the ‘551 and ‘745 patents, entitling Abbott to damages and injunctive relief. Roche and Bayer each allege that they do not infringe the Abbott patents and that the Abbott patents are invalid, thereby entitling Roche and Bayer to declaratory judgments of non-infringement and patent invalidity.

The Court has previously construed several disputed claim terms in coordinated claim construction proceedings. In a claim construction order dated August 31, 2006, the Court construed several terms of the ‘890 and ‘164 patents. In a claim construction order dated April 27, 2007, the Court construed several disputed terms of the ‘551 and ‘745 patents.

LEGAL STANDARD

I. Summary Judgment.

Federal Rule of Civil Procedure 56(c) authorizes summary judgment if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The moving party bears the initial burden of demonstrating the basis for the motion and identifying the portions of the pleadings, depositions, answers to interrogatories, affidavits, and admissions on file that establish the absence of a triable issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party meets this initial burden, the burden then shifts to the non-moving party to present specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *Celotex*, 477 U.S. at 324; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). The non-movant’s bare assertions, standing alone, are insufficient to create a material issue of fact and defeat a motion for summary judgment. *Anderson*, 477 U.S. at 247-48. An issue of fact is material if, under the substantive law of the case, resolution of the factual dispute might affect the case’s outcome. *Id.* at 248. Factual disputes are genuine if they “properly can be resolved in favor of either party.” *Id.* at 250. Thus, a genuine issue for trial exists if the non-movant presents evidence from which a reasonable jury, viewing the evidence in the light most favorable to that party, could resolve the material issue in its favor. *Id.* However, “[i]f the [non-movant’s] evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations

omitted).

A. Non-Infringement.

To determine infringement, the asserted claim must be compared to the allegedly infringing method or device. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). To establish literal infringement, every claim limitation, or claim element, must be found in the accused subject matter. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29, 40 (1997). Thus, establishing that the accused method or device does not satisfy one claim limitation would support a finding of noninfringement. *Id.* The patentee must prove infringement by a preponderance of the evidence. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). Under the doctrine of equivalents, a product that does not literally infringe a patent claim may still infringe if each and every limitation of the claim is literally or equivalently present in the accused device. *See Warner-Jenkinson*, 520 U.S. at 40. Whether an element of an accused product infringes under the doctrine of equivalents depends in part on whether that component performs substantially the same function as the claimed limitation in substantially the same way to achieve substantially the same result. *See Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934-35 (Fed. Cir. 1987) (en banc). If the differences between a claim and an accused device are “insubstantial” to one with ordinary skill in the art, the product may infringe under the doctrine of equivalents. *See Ethicon*, 149 F.3d at 1315; *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997). The doctrine prevents an accused infringer from avoiding infringement by changing minor details of a claimed invention while retaining its essential functionality. *See Sage*, 126 F.3d at 1424.

B. Invalidity.

A patent claim is presumed valid. 35 U.S.C. § 282. The burden is on the party challenging the patent to show, by clear and convincing evidence, that the patent claim is invalid. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986); *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005).

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ANALYSIS

I. Bayer's Motion For Summary Judgment Of Noninfringement.

Bayer seeks summary judgment of noninfringement with respect to the '551 patent for its two accused two products, the Microfill and Autodisc strips. Plaintiffs have accused these two products of infringing claims 1-4 of the '551 patent. Bayer contends that these products do not infringe the asserted '551 claims for two independent reasons: (1) the Bayer products do not contain a "reference electrode", and (2) the Bayer products do not contain electrodes that are in electrical contact with each other.

A. The "reference counterelectrode" limitation.

All of the '551 claims asserted against Bayer cover a device that has a "reference counterelectrode."⁴ In its April 27, 2007 claim construction order, the Court construed "reference electrode" to mean:

an electrode that (1) is used to complete an electrical circuit with the active electrode during the glucose measurement; (2) is positioned or connected in such a way that electricity can flow between the second conductor and the electrode; (3) has a known potential relative to a standard; and (4) maintains its potential with only insignificant variation during the measurement.

Bayer contends that the undisputed evidence establishes that the counterelectrodes contained in its two accused products do not have a known potential relative to a standard.

1. Literal infringement.

The testimony of Bayer's expert, Dr. Stetter, is uncontradicted that the potential of the counterelectrodes in the accused Bayer products varies significantly depending on the concentration of glucose in the sample. (Stetter Decl., ¶¶ 18-25.) Because the purpose of the accused devices is to measure the glucose level in blood, this means that the exact potential of the counterelectrodes is not known before measurement.

In its effort to prove that the potential of the counterelectrodes is nonetheless "known . . .

⁴ Independent claim 1 of the '551 patent contains the "reference counterelectrode" limitation. Claims 2-4 depend from claim 1 and therefore include the limitation as well.

relative to a standard”, Bayer relies exclusively on the testimony of its expert, Jay Johnson.⁵ Dr. Johnson’s testimony describes experiments in which the potential of the counterelectrodes was calculated based on assumptions about the real-world circumstances in which the accused products would be used, and those calculations were then compared with experimentally measured potentials. (Johnson Decl., ¶¶ 44-50.) However, Abbott and Dr. Johnson do not dispute that the potential of the counterelectrodes in the accused Bayer products varies depending on the glucose concentration of the sample (Johnson Decl., ¶¶ 55-56), such that the potential of the counterelectrode in Bayer’s accused products can only be estimated within a range that corresponds to a reasonable range of glucose concentrations encountered in human blood. (Johnson Decl., ¶¶ 22-23; Bartlett Decl., Exh. 11 at 365:7-371:5; Opp. at 6:24-25.) At best, Dr. Johnson’s testimony establishes that the potential of the Bayer counterelectrodes can be narrowed to a range through approximation and experimentation, making assumptions regarding the glucose levels that the accused device would commonly encounter. Dr. Johnson’s testimony, however, fails to create a triable issue of fact as to whether the potential of the Bayer counterelectrodes, which he concedes varies by glucose concentration and cannot be looked up in a reference work, is “known . . . relative to a standard.” Having a range of potentials that can be estimated through calculation and confirmed by experiment does not satisfy the claim limitation as construed by the Court.

Indeed, Abbott and its expert concede facts that conclusively establish that there is no literal infringement under the Court’s construction. Dr. Johnson admits that the counterelectrodes in the Bayer accused products are pseudoreference electrodes. (Johnson Decl., ¶¶ 37-38; *see also* Opp. at 2:15-16, 8:22-23, 9:15-16.) During the claim construction phase, this Court previously rejected Abbott’s contention that the claim term “reference counterelectrode” was broad enough to literally encompass pseudoreference electrodes. Abbott concedes in its opposition that “[t]he Court determined that the reference electrode did not include a quasireference or pseudoreference electrode.” (Opp. at 14:25-15:1.)

Abbott’s experimental tests of the Bayer accused devices, which were performed at a set

⁵ Abbott misstates the burden of proof in its opposition brief. Bayer need not “prov[e] the Accused Products do not infringe.” (Opp. at 4:21.) It is Abbott’s burden to prove, by a preponderance of the evidence, that Bayer’s accused devices infringe the ‘551 patent.

1 glucose concentration, also fail to create a triable issue of fact with respect to the “reference
 2 counterelectrode” claim element. (Johnson Decl., ¶¶ 44-50.) To the extent those tests showed that
 3 the potential of Bayer’s counterelectrodes varied less than a commercial blood glucose sensor with a
 4 Ag/AgCl electrode, as Dr. Johnson contends, the tests are probative of the amount of variation in the
 5 potential during the measurement, but not whether the potential is “known . . . relative to a
 6 standard”, a separate requirement imposed by the Court’s claim construction. Such test results do
 7 not refute that the potential of the Bayer counterelectrode differs significantly depending on the
 8 glucose level of the sample to be tested. Abbott’s tests therefore do not establish that the potential of
 9 the Bayer counterelectrode is “known . . . relative to a standard.”

10 Accordingly, there can be no literal infringement of claims 1-4 of the ‘551 patent because
 11 Bayer’s accused products do not contain a “reference counterelectrode.”

12 **2. Reconsideration of the Court’s claim construction.**

13 In an effort to rescue its literal infringement allegations, Abbott requests that the Court
 14 reconsider its construction of the claim term “reference counterelectrode.” Abbott contends that
 15 subsequent developments since the March 9, 2007 claim construction hearing, including expert
 16 testing and depositions of Defendants’ witnesses, provide new evidence that support a different
 17 construction.

18 As a threshold matter, Bayer argues that it is procedurally improper for the Court to revisit
 19 the accuracy of its construction. Several sister courts have required a litigant to meet the Civil Local
 20 Rule 7-9 standard when requesting reconsideration of a claim construction. *See Celerity, Inc. v.*
 21 *Ultra Clean Tech. Sys. & Serv.*, 2007 U.S. Dist. LEXIS 44490 at *5 (N.D. Cal. June 1, 2007);
 22 *Samsung Elecs. Co. v. Quanta Computer, Inc.*, 2006 U.S. Dist. LEXIS 54538 at *3-4 (N.D. Cal. July
 23 25, 2006); *Ultratech, Inc. v Tamarack Sci. Co.*, 2004 U.S. Dist. LEXIS 21393 at *4 n.1 (N.D. Cal.
 24 Oct. 12, 2004). Though Abbott cites to Federal Circuit decisions indicating that courts “may engage
 25 in a rolling claim construction, in which the court revisits and alters its interpretation of the claim
 26 terms as its understanding of the technology evolves”, these decisions involved avowedly tentative
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1 constructions arrived at in the preliminary injunction context.⁶ In contrast, this Court arrived at its
 2 claim construction after full opportunity for the parties to present evidence relevant to claim
 3 construction consistent with the detailed procedures established by the Northern District's local
 4 rules. The Court will therefore follow the lead of its sister courts and vet Abbott's request for
 5 reconsideration as if it had been brought as a motion for leave to file a motion for reconsideration
 6 under Civil Local Rule 7-9.

7 Against that backdrop, the Court notes that all of the allegedly "new" evidence cited by
 8 Abbott falls into the category of extrinsic evidence, which by its nature plays a very limited role in
 9 the construction of patent claims. Although extrinsic evidence may be used by the Court to help
 10 understand a disputed claim limitation, it may not be used to vary, contradict, expand, or limit the
 11 claim language from how it is defined, even by implication, in the specification or file history. *See*
 12 *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584-85 (Fed. Cir. 1996). "Indeed, where the
 13 patent documents are unambiguous, expert testimony regarding the meaning of a claim is entitled to
 14 no weight." *Id.* at 1584. Here, the Court reached the appropriate construction of the "reference
 15 counterelectrode" limitation based solely on the intrinsic evidence. Under controlling Federal
 16 Circuit precedent, the extrinsic evidence now cited by Abbott would have played a very limited role,
 17 if any, in interpreting the "reference counterelectrode" claim limitation had such evidence been
 18 before the Court at the claim construction hearing. *See id.* at 1584-85.

19 Moreover, for most of the newly submitted extrinsic evidence, Abbott has failed to show that
 20 "in the exercise of reasonable diligence" it could not have provided the evidence at the time of the
 21 claim construction hearing. Civil Local Rule 7-9(b)(1). Abbott makes no such "reasonable
 22 diligence" showing for its citations to Roche's U.S. Patent No. Re36,268, to Nova's U.S. Patent No.
 23 6,258,229, to the December 2006 deposition of Dr. Hill, or to its own expert's tests of its own
 24 products. The Court is not inclined to revisit its claim construction based on extrinsic evidence that
 25 Abbott, in the exercise of reasonable diligence, could have brought to the attention of the Court at
 26 the time of the claim construction hearing.

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 28 ⁶ *Jack Guttman, Inc. v. KopyKake Enters. Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002); *see also Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed. Cir. 1996).

1 In any event, Abbott's reconsideration arguments premised on the '268 patent, the '229
 2 patent, Dr. Hill's testimony, and Dr. Johnson's experiments on Abbott's test strips are unpersuasive
 3 and would not warrant a different construction even if they were considered by this Court. For
 4 example, the Roche '268 patent and the Nova '299 patent, which as extrinsic evidence are of limited
 5 probative value anyway, were filed later than the application of which the '551 patent is a
 6 continuation, and therefore have limited value in explaining how one of ordinary skill in the art
 7 would have interpreted the '551 patent disclosures at the relevant time period.

8 Likewise, the Court is not persuaded to revise its construction based on Dr. Johnson's tests
 9 on Abbott's own Medisense test strips. Abbott contends that Dr. Johnson's tests of the Ag/AgCl
 10 second electrode, not protected by a salt bridge, in Abbott's own "Precision Xtra" strips establish
 11 that even an Ag/AgCl reference counterelectrode would not have a known potential relative to a
 12 standard. Therefore, Abbott argues, the Court's claim construction must be wrong since it would
 13 exclude even the preferred embodiment using the Ag/AgCl reference counterelectrodes disclosed in
 14 the '551 patent. As a threshold matter, Abbott fails to persuade the Court that it should afford any
 15 significant weight to this extrinsic evidence, which tested the performance characteristics of a 2007
 16 commercial device, for purposes of determining what a person of ordinary skill would understand
 17 from the teachings of the '551 patent in the mid-1980s. Moreover, the data that Dr. Johnson attaches
 18 to his declaration (Johnson Decl., Exh. 6) does not appear to support his statement (Johnson Decl., ¶
 19 18) that the potential of the Ag/AgCl second electrode in the Abbott commercial device differed to
 20 any significant degree from the known potential of a true Ag/AgCl electrode. The data provided to
 21 the Court indicates that the potential of the Ag/AgCl second electrode, during relevant measurement
 22 times, remained remarkably close in potential (between -0.01 V and 0.00 V) versus a true Ag/AgCl
 23 (3M KCl) electrode. (Johnson Decl., Exh. 6.) The Court is not persuaded that Dr. Johnson's tests
 24 on the Abbott commercial device establish that an Ag/AgCl counterelectrode, unprotected by a salt
 25 bridge, would fall outside the scope of the Court's current claim construction.⁷

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 27 ⁷ Nor does the testimony of Dr. Johnson or Dr. Stetter establish, as Abbott contended at oral argument, that
 28 variations in potential due to varying chloride concentrations in blood would cause even an Ag/AgCl second electrode to have
 an unknown potential relative to a standard. Dr. Johnson's cursory testimony on this point indicates only that chloride
 concentration "can affect" the potential of such a second electrode (Johnson Decl. ¶ 18), but does not indicate the

Abbott's citation to Dr. Hill's December 2006 testimony also does not warrant a change in the claim construction. Dr. Hill conceded that the potential of an Ag/AgCl electrode could drift somewhat over time after enough of the AgCl had converted to Ag through a chemical reaction. (Hill Depo. at 98-100, Hutcheson Decl., Exh. 8; Hill Depo. at 96-97, Hutcheson Decl., Exh. 8A.) However, this testimony does not on its own suggest that an Ag/AgCl counterelectrode would fall outside the scope of the Court's construction, since the construction requires that the reference counterelectrode maintain its potential with insignificant variation only "during the measurement", not indefinitely. Dr. Hill also provided somewhat ambiguous testimony that equates the function of a pseudoreference with the combination of a reference electrode and a counterelectrode. (Hill Depo. at 93-94, Hutcheson Decl., Exh. 8A.) But this testimony, which from the context of the questioning appears to be based on Dr. Hill's 2006 understanding of the term "pseudoreference", is minimally probative of how one skilled in the art would have understood the term "reference counterelectrode" in the mid-1980s.

The only evidence presented by Abbott on the issue of reconsideration that appears to be "new" within the meaning of Civil Local Rule 7-9 is evidence, in the form of deposition testimony and internal documents, concerning how Bayer and other defendants sometimes referred to the counterelectrodes in their accused products. (*See* evidence cited at pages 17-21 of Abbott's Opposition.) This evidence does not provide a sufficient basis for the Court to revise its construction of the "reference counterelectrode" claim term. Testimony by certain employees of Bayer or of other defendants, acknowledging that they have in more recent years used the word "reference electrode" to describe the counterelectrodes used in the accused products, is not sufficiently probative evidence of what one skilled in the art in the mid-1980s would have understood the '551 patent to mean by "reference counterelectrode." Abbott has not demonstrated that these individuals were using terms consistent with how one skilled in the art would have used them in the mid-1980s. Without such a link, such deposition testimony is not the kind of extrinsic

circumstances where this would happen nor the magnitude of such a change. Dr. Stetter's testimony indicates only that a commercial Ag/AgCl reference "resides in a solution of known chloride ion concentration" (Stetter Decl., ¶ 17), but does not state that variations of chloride concentration in blood would render the potential of an Ag/AgCl second electrode unknown relative to a standard.

evidence that plays a significant role in claim construction.

Accordingly, the Court finds no basis to alter its construction of the “reference counterelectrode” claim term.

3. Doctrine of equivalents.

Abbott contends that the jury could still find infringement under the doctrine of equivalents (DOE) because the “pseudoreference” counterelectrode used in the Bayer accused devices is an “insubstantial difference” from the “reference counterelectrode” required by the ‘551 claims.⁸ Abbott argues that even if the potential of the counterelectrodes in the Bayer accused products is not “known . . . relative to a standard”, the Bayer counterelectrodes are nonetheless an equivalent.

Abbott has adduced sufficient evidence to create a triable issue of fact as to whether a pseudoreference is an insubstantial difference from the “reference counterelectrode” required by the ‘551 claims. Abbott submits considerable evidence that those with ordinary skill in the art would today consider a pseudoreference electrode to be interchangeable with a reference electrode. Known interchangeability is a useful objective standard of equivalency. *See Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 36 (1997). Abbott’s expert, Dr. Johnson, has testified in detail regarding the similarities between reference electrodes and pseudoreference electrodes (Johnson Decl., ¶¶ 15-23), and opines that for many years those of ordinary skill in the art “have known of the interchangeability of the terms pseudoreference electrode and reference electrode in blood glucose sensors” (Johnson Decl., ¶ 32). Similarly, Bayer scientist Dr. Vreeke acknowledged that if he had been told in 1999 to use any type of reference electrode to make a blood glucose sensor, he would have understood he could use a quasireference electrode. (Vreeke Depo. at 263:11-18, Hutcheon Decl., Exh. 6.) Relevant art in the field such as the Roche’s ‘268 patent also supports the interchangeability of pseudoreference electrodes with reference electrodes, stating: “The reference electrode may also be of the type generally known as a ‘pseudo’ reference electrode which relies upon the large excess of the oxidizing species to establish a known potential at a noble metal electrode.” (Johnson Decl., Exh. 11 at 6:11-19.) Dr. Hill’s testimony equating the function of a

⁸ For purposes of its noninfringement motion, Bayer does not contest that Abbott’s characterization of the counterelectrodes in the accused devices as pseudoreferences is correct. (Reply at 2:1-2.) Bayer has reserved for trial the argument that its counterelectrodes do not even qualify as pseudoreferences.

pseudoreference with the combination of a reference electrode and a counterelectrode also suggests equivalency. (Hill Depo. at 93-94, Hutcheson Decl., Exh. 8A.) Finally, the evidence that Abbott has submitted indicating that Defendants themselves sometimes referred to the counterelectrodes used in their accused products as “reference” electrodes, although not a sufficient basis for reconsideration of the Court’s construction for the reasons discussed above, is certainly probative evidence that one of ordinary skill in the art might consider pseudoreference electrodes and reference electrodes to be interchangeable.⁹ In short, the Court finds that Abbott has provided sufficient particularized testimony and linking argument as to the insubstantiality of the differences between a pseudoreference electrode and a reference counterelectrode (as defined by the ‘745 patent) to create a triable issue of fact regarding infringement by equivalents. *See Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1363 (Fed. Cir. 2005).

The Court disagrees with Bayer that Abbott’s infringement-by-equivalents argument violates the precept that the doctrine of equivalents cannot be used to vitiate an entire claim element. *See Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1339 (Fed. Cir. 2004). Abbott’s theory of infringement by equivalence would not automatically read the “reference” part of the “reference counterelectrode” claim limitation out of the claim, because the evidence submitted by Abbott indicates that a pseudoreference counterelectrode has properties that make the potential of the pseudoreference more predictable and less variable than a mere counterelectrode. On this record, Abbott is not foreclosed from arguing that pseudoreference counterelectrodes are an equivalent to the “reference counterelectrode” claim limitation.

Accordingly, there is a triable issue of fact as to whether there is infringement by equivalents by Bayer’s accused products of the “reference counterelectrode” limitation in the ‘551 patent claims.

B. The “electrical contact” limitation.

As an independent ground for a finding of noninfringement of the ‘551 patent, Bayer asserts that the undisputed record indicates that the two electrodes in Bayer’s accused products are not in

⁹ “Insofar as the question under the doctrine of equivalents is whether an accused element is equivalent to a claimed element, the proper time for evaluating equivalency-and thus knowledge of interchangeability between elements-is at the time of infringement, not at the time the patent was issued.” *Warner-Jenkinson*, 520 U.S. at 37.

1 electrical contact before the blood sample is applied.¹⁰ The Court disagrees.

2 The asserted ‘551 claims all require that the active electrode not be “in electrical contact”
3 with the reference counterelectrode before the blood sample is applied. The Court, in construing this
4 claim limitation, has determined that two items are in electrical contract if they are “positioned or
5 connected in such a way that electricity can flow” between them.

6 Here, Abbott’s expert, Dr. Johnson, has submitted testimony regarding experiments that
7 measured the resistance between the two electrodes in the accused Bayer products. The tested Bayer
8 products were commercial strips subjected to experimentation after they were removed from the vial
9 in which Bayer sells them. (Alva Decl., ¶ 4.) Accordingly to Dr. Johnson, the experiment did not
10 detect any resistance below 50 megaohms. (Johnson Decl., ¶ 62.) Dr. Johnson opines that one of
11 ordinary skill in the art would expect the meter to provide a resistance measurement below this 50
12 megaohm threshold if there were an electrical connection between the two electrodes. (Johnson
13 Decl., ¶¶ 62-63.) Bayer raises no argument in its motion that Dr. Johnson’s testimony regarding the
14 resistance experiment is inadmissible or unreliable. The Court finds that, based on Dr. Johnson’s
15 testimony, a reasonable jury could conclude that the two electrodes are not in electrical contact with
16 each other before the blood sample is applied.

17 Despite Dr. Johnson’s tests, Bayer contends that certain deposition admissions by Dr.
18 Johnson, coupled with the tests of Bayer’s own expert, establish as an undisputed fact that there is an
19 electrical connection between the two electrodes before the sample is applied. Bayer’s expert, Dr.
20 Stettler, has submitted testimony that describes experiments that measured the flow of current
21 between the two electrodes in the Bayer accused products under a variety of humidity and
22 temperature conditions. (Stettler Decl., ¶¶ 28-30.) The current measurements ranged from -5.4
23 picoamps (pA) to 48,111 pA for the Bayer Microfill, depending on temperature and humidity
24 conditions. (*Id.*, ¶ 30.) The current measurements ranged from -14 pA to 43,534 pA for the Bayer
25 Autodisc, depending on temperature and humidity conditions. (*Id.*) Although Dr. Johnson conceded
26 in deposition that a current in the range of 5,000 pA would establish “electrical contact” between the
27

28 ¹⁰ Abbott’s has not asserted infringement under the doctrine of equivalents for the electrical contact limitation.
Therefore, this Court’s analysis is limited to literal infringement only.

two components (Johnson Depo. at 344:11-16, Bartlett Decl., Exh. 11), this current threshold was exceeded in Bayer's experiments only under conditions in which the ambient humidity exceeded 75%. (Stettler Decl., Exh. E.) At lower humidity values of 25% or 50%, and for the Microfill product even at lower temperatures at 75% humidity, the measured current was below 2000 pA. (*Id.*)

Though Bayer posits that its tests show that the reagent layer on the Bayer accused products provides an electrical path between the active and counterelectrodes even before blood is applied, the proper interpretation of the results of Bayer's tests of its own products is not undisputed on this record. Bayer's own data, together with Dr. Johnson's alternative explanations for Bayer's experimental results, raise triable issue of facts as to what conclusions can be drawn from Bayer's tests. To begin with, Dr. Stettler himself admitted that the current measurements of less than 50pA are "unreliable or basically within noise." (Stetter Depo. at 150:20-151:2, Hutcheson Decl, Exh. 11). All currents tested on the Bayer products at 25% humidity fell below this 50 pA "noise" threshold. (Stetter Decl., Exh. E.) Dr. Johnson's analysis of these data points raises a question as to whether the measurements at higher humidity accurately reflected real-world conditions. (Johnson Decl., ¶ 69; Alva Decl., ¶ 5.) Moreover, Dr. Johnson's testimony suggests that the sharp, twenty-fold jump in measured current that occurred only when 75% humidity conditions were imposed may merely be a form of ionic current that occurs when the reagent layer absorbs enough moisture from the air, rather than an electrical connection that is always present. (Johnson Decl., ¶ 70.)

On this record, triable issues of fact remain as to whether the "electrical contact" limitation is satisfied by the Bayer accused products. The Court therefore cannot make a finding of noninfringement at the summary judgment stage based on this claim limitation.

II. Roche's Motion For Partial Summary Judgment Of Noninfringement.

Roche seeks summary judgment of noninfringement with respect to the '745 patent for its accused product, the Aviva system. Roche contends that the Aviva does not infringe the '745 claims asserted against it (claims 1-5, 8, 11, 21-23, 28, 31 and 34) for two independent reasons: (1) no mediator is present on the Aviva test strip prior to touching the sample to the test strip; and (2) Abbott had no admissible evidence that the Aviva strip contains a measurement zone as defined by

1 the '745 patent.

2 **A. Mediator on the Aviva test strip.**

3 Each of the independent claims of the '745 patent – claims 1, 28 and 34 – describe a method
4 comprising multiple steps, wherein the first step is described as: “contacting a sample with an
5 electrochemical sensor comprising: (i) an electrode pair . . . , (ii) a measurement zone, and, (iii) an
6 analyte-responsive enzyme and a diffusible redox mediator.” (Tyler Decl., Exh. 1.) In their March
7 30, 2006 Revised Joint Claim Construction Statement submission pursuant to Patent Local Rule 4-3,
8 Abbott and Roche agreed this language means “[a]n electrochemical sensor, which includes two
9 electrodes, a measurement zone, an analyte-responsive enzyme and a diffusible redox mediator, to
10 which electrochemical sensor a sample is touched.” Abbott asserts literal infringement, but not
11 infringement by equivalents, of this claim limitation.

12 As a threshold issue, the parties diverge in their views of how the claim limitation, and even
13 their agreed-upon construction, should be applied to the Aviva test strip. For purposes of Roche’s
14 motion, it is undisputed that a diffusible redox mediator, in the form of
15 quinonediimine/phenyldiamine, gets formed on the Aviva test strip once the blood sample contacts
16 the nitrosoaniline precursor that is present on the test strips before sample application.¹¹ However,
17 Roche contends that the claim limitation requires that the sensor include a diffusible redox mediator
18 before it is ever contacted by the blood. Therefore, Roche argues, there can be no infringement
19 because Abbott is unable to prove that the Aviva test strip includes a diffusible redox mediator
20 before it comes into contact with the blood sample. Abbott disagrees with Roche’s reading of this
21 claim limitation, and contends that this claim limitation does not impose any temporal restrictions.
22 Thus, Abbott argues, the claim limitation is satisfied if at some point while the blood sample is in
23 contact with the electrochemical sensor, the electrochemical sensor includes a diffusible redox

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25 ¹¹ The parties do take different positions as to whether a diffusible redox mediator is present on the Aviva test strip
26 even earlier than when the blood sample first contacts the sensor. First, the parties disagree as to whether the chemical pair
27 quinonediimine/phenyldiamine, which is undisputedly a mediator, is present on the strip even before introduction of the
28 blood. Second, the parties also disagree as to whether the nitrosoaniline “precursor”, which is undisputedly present on the
strip before introduction of the blood itself, itself constitutes a diffusible redox mediator. Abbott filed a surreply, and Roche
a further response to that surreply, directed at both disagreements. However, in light of the Court’s finding that Roche’s non-
infringement theory raised is foreclosed by a proper reading of this claim limitation, the Court need not resolve whether the
evidence submitted by the parties creates a triable issue as to either of these areas of disagreement.

1 mediator. Because there is no dispute for purposes of this motion that a diffusible redox mediator is
2 present in the Aviva sensor after the blood sample contacts the Aviva strip, but while the blood
3 sample is still in contact with the strip, Abbott argues the claim limitation is met.

4 Turning first to the parties' agreed-upon construction, the Court disagrees with Roche that
5 the agreed-upon construction clearly establishes a temporal limitation on when a mediator must be
6 present relative to when the blood first encounters any parts of the electrochemical sensor. The
7 parties' agreed-upon construction of the claim term requires "[a]n electrochemical sensor, which
8 includes two electrodes, a measurement zone, an analyte-responsive enzyme and a diffusible redox
9 mediator, to which electrochemical sensor a sample is touched." Although there is some ambiguity
10 in the parties' selected phrasing, this agreed-upon construction does not necessarily require that, at
11 the *first* moment any part of the sensor and the sample are touched together, the sensor must already
12 include a diffusible redox mediator. For example, if at "time zero" the sample encounters the sensor
13 but the sensor does not yet include a mediator, and at "time one" the sensor includes a mediator and
14 the sample continues to touch the sensor, the parties' agreed-upon construction would appear to be
15 satisfied by the event occurring at "time one." There would, at "time one", be an electrochemical
16 sensor (now including the mediator) "to which electrochemical sensor a sample is touched."

17 The Court further finds that basic claim construction principles provide a strong reason to
18 reject Roche's assertion that the claim term requires the sensor to include a diffusible redox mediator
19 at the time the blood sample first contacts the sensor. A necessary predicate to Roche's
20 interpretation is the assumption that the step of "contacting a sample with an electrochemical sensor"
21 is an instantaneous event that occurs at a single point in time – namely, the point in time where the
22 blood first encounters the sensor. Claim construction principles cut against this assumption.

23 As Abbott persuasively pointed out at oral argument, interpreting the step of "contacting a
24 sample with an electrochemical sensor" to encompass only a single moment in time would be flatly
25 inconsistent with several of the dependent claims in the '745 patent. In particular, dependent claims
26 26, 29 and 37 claim a method "wherein the contacting step includes drawing the sample into the
27 sensor through an opening at the edge of the sensor from the skin of the patient into the sensor and
28 into the circular recess to contact the working electrode." Dependent claims 32 and 35 claim a

1 method “wherein the contacting step includes drawing the sample into the sensor through an opening
2 at an end edge of the sensor strip from the sample on the skin of the patient into the sensor and first
3 contacting a first of the working electrodes and then contacting a second of the working electrodes.”
4 Thus, each of these dependent claims describe the contacting step as “including” multiple non-
5 simultaneous events that occur even after the sample first contacts the sensor. It would be
6 incongruous, and would render the ‘745 patent claims internally inconsistent, if the Court interpreted
7 the contacting step as an event limited to a single point in time, as proposed by Roche.

8 The Court is further convinced that Roche’s interpretation cannot carry the day because the
9 Court finds no real support in the patent’s claims or specification for Roche’s interpretation of the
10 “contacting step” limitation. At oral argument, Roche argued that the mention in dependent claims
11 32 and 35 of “first contacting” and “second contacting” sheds light on how the claim drafters
12 intended to use the word “contacting” to refer to an instantaneous event. The Court parses these
13 words differently. It is the use of the ordinals “first” and “second” in dependent claims 32 and 35
14 that narrow the relevant inquiry to specific points in time for purposes of those dependent claims.
15 The same cannot be said of the phrase “contacting . . . with”, which is used to described the
16 contacting step and does not limit the step to a single point in time. The Court also cannot ascribe
17 significant weight to the portions of the specification that Roche cites in its reply brief, which are all
18 discussions of specific or preferred embodiments. (‘745 patent, cols. 3:24-27, 9:57-58, 23:57-59 &
19 45:18-21.) It is not appropriate to read these aspects of preferred embodiments into the claim
20 language.

21 Accordingly, the Court is persuaded that the “contacting step” is not limited to a single point
22 in time. Roche’s non-infringement argument presented in its motion therefore cannot prevail at
23 summary judgment, because even under Roche’s version of how the Aviva strip operates, the claim
24 limitation is satisfied as of the moment the mediator forms on the sensor, given that the blood
25 sample is still contacting the sensor at that time. Once the mediator forms from a reaction of the
26 blood sample and the precursor chemical, there is a sensor including a mediator “to which
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1 electrochemical sensor a sample is touched.”¹²

2 Because there is, at a minimum, a triable issue of fact as to whether the “contacting step”
3 claim limitation in the ‘745 patent is met by the Aviva strip, summary judgment of noninfringement
4 on this ground is not appropriate.

5 **B. “Measurement zone” limitation.**

6 As a second and independent basis for a finding of noninfringement, Roche contends that
7 Abbott has identified no admissible evidence that the Aviva strip contains a measurement zone as
8 defined by the ‘745 patent. The Court disagrees.¹³

9 The ‘745 patent claims describe a method for determining a concentration of glucose in a
10 sample by using an electrochemical sensor comprising, inter alia, “a measurement zone positioned
11 adjacent to the working electrode and the counterelectrode, wherein the measurement zone is sized
12 to contain a volume of no more than about one microliter of the sample.” The inventors of the
13 patent, acting as their own lexicographers, specifically defined the measurement zone as “a region of
14 the sample chamber sized to contain only that portion of the sample that is to be interrogated during
15 an analyte assay.” (‘745 patent at 7:7-10.) The parties expressly stipulated to this definition of
16 “measurement zone” during the claim construction process.

17 With the parties’ agreed-upon construction as a backdrop, Dr. Bard’s expert testimony
18 provides a factual basis upon which a reasonable jury could conclude that the Aviva test strip
19 contains a measurement zone. Dr. Bard’s testimony correlates the concept of “sample that is to be
20 interrogated” in the parties’ stipulated definition with sample that is placed in the electric field
21 between the electrodes in the system. (Bard Decl. , ¶ 23.) Dr. Bard then provides testimony that

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23 ¹² The Court notes that other arguments advanced by Abbott in support of its interpretation miss the mark and were
24 not relied upon by the Court. For example, Abbott argues that the steps of a method claim do not need to be performed in
25 order unless that is implicitly required. While true, this analysis is not dispositive, as the *components* of the sensor articulated
26 in the patent claims are not separate *steps* of the claimed method. Abbott also cites to Example 9 of the ‘745 Patent as an
27 example disclosed in the patent where a mediator precursor is not converted to a mediator until the sensor is touched by the
sample. But there is no principle, or presumption, that the claims cover everything disclosed in the specification. To the
contrary, “when a patent drafter discloses but declines to claim subject matter, as in this case, this action dedicates that
unclaimed subject matter to the public.” *Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co., Inc.*, 285 F.3d 1046, 1054 (Fed.
Cir. 2002). There is simply no requirement that the claims, as issued, cover Example 9.

28 ¹³ As explained below in connection with Defendants’ motion for summary judgment of invalidity with respect to
the ‘745 patent, the Court finds that the “measurement zone” claim limitation is not indefinite.

1 indicates a measurement zone is located within the Aviva test strip, whether the measurement zone
2 is intended to be a geometric space that only approximates the sample that is placed into the electric
3 field between the electrodes (Bard Decl., ¶ 49), or is more strictly drawn to correspond precisely to
4 the sample placed in this electric field during measurement (Bard Decl., ¶ 53).

5 Roche attacks the sufficiency of Dr. Bard's testimony in several ways. First, Roche contends
6 that Dr. Bard's testimony fails to competently establish that the Aviva strip includes a physical space
7 that "contain[s] only that portion of the sample that is to be interrogated during an analyte assay", as
8 required by the parties' agreed-upon construction. To be sure, the portions of Dr. Bard's testimony
9 directed to his view that the measurement zone may be only a geometric space that "approximates
10 the sample that is interrogated" (Bard Decl., ¶¶ 24, 49-52) may well suffer from this deficiency.
11 However, Dr. Bard also offers a separate back-up analysis that competently indicates that even if the
12 contours of the measurement zone are drawn to include exactly the sample in the sample chamber
13 that is in the electric field, the Aviva test strip would still contain a measurement zone meeting the
14 requirements of the '745 claims. (Bard Decl., ¶ 53.) The Court finds that this testimony raises at
15 least a triable issue of fact as to whether the Aviva strip includes a physical space that "contain[s]
16 only that portion of the sample that is to be interrogated during an analyte assay."

17 Dr. Bard concedes that, under his back-up analysis, he cannot know the precise boundaries of
18 all sides of the measurement zone in the Aviva test strip without performing a finite element
19 analysis, which he has not done. (Bard Decl., ¶¶ 28-29, 53.) Roche suggests that this constitutes a
20 failure of proof on Dr. Bard's part, but the Court disagrees. Dr. Bard testifies as to how he can
21 deduce the existence of a region of the sample chamber that contains only the portion of the sample
22 that is to be interrogated, even though he has not identified its exact size or all of its boundaries. To
23 prove infringement, the '745 patent claims do not necessarily require Abbott to establish the exact
24 boundaries of the measurement zone, so long as it can prove by a preponderance of the evidence that
25 there exists a zone that "contain[s] only that portion of the sample that is to be interrogated during an
26 analyte assay" and that satisfies the other requirements placed upon the measurement zone by the
27 '745 claims. Dr. Bard's testimony provides a basis on which a reasonable jury could conclude there
28 is a measurement zone in the Aviva test strip that satisfies the '745 claim requirements, and his

1 testimony is not rendered insufficient merely because he cannot identify the precise contours of the
2 measurement zone in all dimensions.

3 Roche points to the testimony of its own expert, Dr. Weber, who opines that there is no
4 measurement zone in the Aviva test strip based on his analysis that the only portion of the sample
5 that is “interrogated” in the Aviva test strip is the sample to which the mediator can diffuse from the
6 working electrode before the measurement is completed. (Weber Decl., Exh. 1 at 37-41.) Roche
7 contends that Dr. Weber’s opinions of non-infringement are “unrebutted” on this record (Reply at
8 9:16-17), but they are not. At a minimum, Dr. Bard’s testimony creates a triable issue of fact as to
9 whether the sample that is “interrogated” in the Aviva test strip includes only that sample that
10 encounters the diffusing mediator, or includes the sample that is located in the electric field between
11 the electrodes during measurement. Dr. Bard’s testimony also specifically critiques several of Dr.
12 Weber’s underlying assumptions as being inconsistent with the discussion of the measurement zone
13 in the ‘745 specification (Bard Decl., ¶¶ 36-48), upon which a reasonable jury could rely to reject
14 some or all of Dr. Weber’s ultimate opinions of non-infringement.¹⁴ The deposition testimony of
15 another of Roche’s experts, Dr. Surridge, also provides a basis upon which a reasonable jury could
16 reject some or all of Dr. Weber’s opinions, given that he indicated that some of the assumptions
17 made Dr. Bard about the measurement zone were as reasonable as the diffusion-based analysis
18 provided by Dr. Weber. (Surridge Depo. at 414-46; Hutcheson Supp. Decl., Exh. A.)

19 Accordingly, the Court finds that, on this record and using the parties’ agreed-upon
20 construction, there is a triable issue of fact as to whether the Aviva strip has a measurement zone.

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24 ¹⁴ For example, the ‘745 specification suggests the volume of the measurement zone can be defined and known in
25 advance, based on the physical structure of the device, before any blood sample is applied, and without respect to the type
26 of measurement or measurement time. (‘745 patent at 25:24-29; 25:39-40, 26:66-27:4, 27:21-25; 28:6-12, 28:45-49, 31:31-
27 37.) The ‘745 specification also refers to the measurement zone as a space that is pre-existing, that can be “empty” as the
28 blood sample enters the device, that can be partially filled with material such as glass beads, that blood sample can pass
through before measurement starts, and then at some point gets “filled.” (‘745 patent at 29:65-30:6, 30:49-57, 38:28-31,
41:43-46, 42:5-23, 58:16-17.) The ‘745 specification further indicates that glucose can diffuse into the measurement zone
from portions of the sample chamber outside the measurement zone and cause errors in the measurement. (‘745 patent at
27:3-39.) These statements in the ‘745 specification are in tension with Defendants’ modeling of the measurement zone
through a diffusion analysis. The Court cannot, as Roche urges, adopt Dr. Weber’s analysis as the only reasonable expert
testimony in the record applying the measurement zone concept to the Aviva test strip.

III. BD/Nova's Motion For Summary Judgment Of Non-Infringement.

In its motion for summary judgment of non-infringement, BD/Nova contends that the BD test strip does not infringe any of the asserted claims of the '745, '164, or '551 patents as a matter of law.

A. The "non-flowing manner" limitation of the '164 and '745 patents.

Abbott assert claims 16, 20, 22, 23, 26, 27, 34, 36-38, and 40 of the '164 patent, and claims 1, 3-5, 8, 11, 21-23, 26-30, 34, 37, and 38 of the '775 patent, against BD/Nova. All of the asserted claims of the '164 and '745 patents require that the blood sample be held within the strip in a "non-flowing manner." BD/Nova contends that because the blood sample within the BD test strip's measurement zone flows for the entire measurement time, this claim limitation is not met by the BD test strip, and there is therefore no infringement of the '164 and '745 patents.

In its August 31, 2006 claim construction order regarding the '164 patent, the Court construed "holding the sample in a non-flowing manner within the sample chamber of the analyze sensor" to mean that "the sample is not moving in the sample chamber during the measurement." The Court determined that a sample that was even "flowing at a very slow rate" is "directly at odds with the plain and ordinary meaning of "non-flowing." In its July 10, 2007 summary judgment order, the Court further indicated that this construction meant "something other than preventing the sample from leaving the measurement zone – it requires that 'the sample is not moving in the sample chamber during the measurement."

The undisputed record before this Court establishes that the blood sample within the working electrode well in the BD test strip has a convective flow during the measurement period. BD/Nova's experts present competent evidence, in the form of both expert testimony and videotaped footage of experiments, that the blood sample within the working electrode well in the BD test strip exhibits a rotational swirling effect during measurement. (Durgin Decl., ¶¶ 7-13; Wilson Decl., ¶¶ 6-8 & Exhs. 2-7.) Abbott's expert, Dr. Bard, does not dispute the methodology used in these observations and experiments. To the contrary, Dr. Bard conceded that these experiments showed that there is a "small amount of swirling" during measurement. (Bard Depo. at 483:11, Dahiya Decl., Exh. 6; *see also id.* at 475:14 ("It looks like, in that strip that I've seen, that there's a slight swirling in the

chamber’’)). Dr. Bard concedes that this observed rotational swirling is not Brownian motion (*id.* at 490:13), and is not diffusion (*id.* at 490:15), but instead “appears to be a convective flow” (*id.* at 490:17).¹⁵

Against this backdrop, having reviewed the evidence submitted by Abbott, the Court concludes that Abbott has failed meet its burden of introducing evidence that would permit a reasonable jury to conclude that the sample is not moving in the sample chamber during the measurement. The sole evidence on which Abbott relies is the testimony of its expert, Dr. Bard. However, Dr. Bard’s testimony provides no evidence that could support a finding of infringement here.

Dr. Bard’s stated opinion regarding the BD test strip in his declaration is that “[t]here is no bulk movement of the sample with respect to the sample chamber in Defendants’ test strips after they have filled.” (Bard Decl., ¶ 59.) Although Dr. Bard then purports to base this conclusion on observations that he made, the entirety of Dr. Bard’s testimony regarding any actual observations of BD test strips reads as follows:

[I]f there were movement of the sample, one would expect to see movement at either end of the sample chamber where resistance to movement is lowest. However, I observed no such movement in any of Defendants’ test strips. Video Exhibits 1 and 2.

Dr. Bard’s testimony is insufficient to create a triable issue of fact regarding the “non-flowing manner” claim element for at least two reasons. First, Dr. Bard’s ultimate opinion that “[t]here is no bulk movement of the sample to the sample chamber” is conclusory and insufficiently supported by foundational facts on this record. His declaration provides no information regarding the circumstances or conditions of any observations he made. Although his declaration references two video exhibits, it does not authenticate these exhibits, let alone describe the video’s origins, the circumstances in which the videos were made, or what the videos depict. (Bard Decl., ¶ 59.)

¹⁵ Although Dr. Bard specifically referred to the rotational swirling seen in Defendant’s experiments as “a convective flow”, Dr. Bard has also described convection generally as a form of flow:

Q. Okay. And you have a convective – and convection means flow, does it not?

A. Convection means that there’s a velocity gradient within the solution somewhere.

Q. And that means flow in the solution?

A. I guess the not technical term would be flow.

(Bard Depo. at 495:9-14; Dahiya Decl., Exh. 29.)

1 Elsewhere, Dr. Bard's declaration "incorporates by reference" pages 6-9 and Exhibits 3 & 5 of his
2 infringement expert report (Bard Decl., ¶ 76), but even his infringement report does not provide any
3 foundational facts regarding any observations that he conducted of the BD test strip, beyond the
4 threadbare assertion in his expert report that he has "personally observed the accused strips filling. . .
5 ." (Bard Decl., Exh. 3 at p. 6.) Dr. Bard's testimony contains no other facts regarding the
6 circumstances of his "observations." Dr. Bard therefore fails to lay an adequate foundation for his
7 ultimate conclusion that "[t]here is no bulk movement of the sample with respect to the sample
8 chamber", because he provides no information regarding the circumstances or procedures or
9 experimental conditions in which he observed the BD test strips. On this record, a jury could not
10 reasonably regard Dr. Bard's opinion as grounded in reliable data. A jury therefore could not
11 reasonably rely on either Dr. Bard's observations of the BD test strip or on his ultimate conclusion
12 that there is no bulk movement of the sample with respect to the sample chamber in the BD test
13 strip. This leaves Abbott with a complete failure of proof.

14 Second, and more fundamentally, even if a jury could reasonably rely on Dr. Bard's
15 opinions, his testimony makes clear that his observations and conclusions do not speak to the
16 question of whether the sample is moving *within* the sample chamber during the measurement. His
17 testimony is therefore insufficient to establish that this claim limitation, as construed by the Court, is
18 met. Dr. Bard's ultimate opinion is limited to the observation that "the bulk sample itself is not
19 moving" (Bard Decl., ¶ 60) and to the question of whether there is "bulk movement of the sample
20 with respect to the sample chamber" (Bard Decl., ¶ 59). Importantly, Dr. Bard nowhere opines that
21 there is not movement of the sample *within* the sample chamber. He opines, merely, that there is not
22 "bulk movement" because he observed no movement of the sample "at either end of the sample
23 chamber." (Bard Decl., ¶ 59.) His expert report further confirms that his opinion was premised on
24 his observation that "there is no discernable flow into or out of the sample chamber" (Bard Decl.,
25 Exh. 3 at 7) and "no movement of the bulk sample in the thin capillary chamber during the
26 measurement" (Bard Decl., Exh. 3 at Exh. 5, at 3).

27 Such testimony about bulk movement of the entire sample, based on whether the sample was
28 flowing into or out of the sample chamber at the edges, does not create a triable issue of fact as to

whether the sample is moving within the sample chamber, particularly given Dr. Bard's frank admissions at deposition that he observed "swirling", which he equates with "convective flow" and "mass transfer", within the sample chamber. A reasonable jury would have to find, on this record, that there is convective flow in the sample in the working electrode well during measurement, and could not reasonably infer otherwise from Dr. Bard's conclusions, even if a reasonable jury considered those conclusions to be based on reliable observations.

Dr. Bard's opinions concerning the use of Cottrell-type measurements in the BD test strips also do not create a triable issue of fact. Dr. Bard's declaration itself concedes that Cottrell-type measurements would still work where there is "minimal" convective flow. (Bard Decl., ¶ 61.) At deposition, he also agreed with the statement that "you can have a system with a small amount of convection in the system and the Cottrell equation will still apply." (Bard Depo. at 494:21-24; Supp. Dahiya Decl., Exh. 29.)

Finally, Dr. Bard's opinions concerning the meaning of the Court's claim construction, even if admissible, would not prevent a finding of non-infringement. Dr. Bard opines that the Court's construction should not be read so expansively as to exclude all motion, since Brownian motion and diffusion are present in every liquid. (Bard Decl., ¶ 60.) The Court need not resolve this issue to resolve the motion, however, because Dr. Bard has conceded that the motion observed in the active electrode well of the BD test strip is neither Brownian motion or diffusion, but is convective flow. Even if Brownian motion and diffusion within the sample chamber should not be precluded by the Court's construction, the convective, swirling movement that Bard has conceded exists in the BD test strip is enough to remove the BD test strip from the literal scope of the asserted '164 and '745 patent claims. Because Abbott raises no argument that there is infringement under the doctrine of equivalents,¹⁶ summary judgment of non-infringement is appropriate on this record.

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¹⁶ Because Abbott has submitted no particularized testimony or linking argument with respect to this claim limitation as to the "insubstantiality of the differences" between the claimed invention and the accused device or process, or with respect to the function, way, result test, there is no triable issue of fact as to infringement under the doctrine of equivalents. See *Network Commerce*, 422 F.3d at 1363.

B. The “measurement zone positioned adjacent to the working electrode and the counter electrode” limitation of the ‘745 patent.

As an alternate basis for summary judgment of noninfringement of the ‘745 patent, BD/Nova contends that the BD Test Strip’s measurement zone is not adjacent to the counter electrode, and therefore there can be no infringement of the ‘745 patent.

In its April 27, 2007 claim construction order, the Court construed the ‘745 claim limitation “measurement zone positioned adjacent to the working electrode and the counter electrode” to mean “the measurement zone is next to (whether or not touching) both the working electrode and counter electrodes, with no other structure intervening between either electrode and the measurement zone.” The parties have stipulated, based on an express definition in the ‘745 patent, that the term “measurement zone” means “a region of the sample chamber sized to contain only that portion of the sample that is to be interrogated during the analyte assay.” (Dahiya Decl., Exh. 11 at 7:7-9.)

With the parties’ agreed-upon construction as a backdrop, Dr. Bard’s expert testimony provides a factual basis upon which a reasonable jury could conclude that the BD test strip’s measurement zone is adjacent to both electrodes. Dr. Bard’s testimony correlates the concept of “sample that is to be interrogated” in the parties’ stipulated definition with sample that is placed in the electric field between the electrodes in the system. (Bard Decl., ¶ 23.) Dr. Bard then provides testimony that indicates a measurement zone is located within the BD test strip, whether the measurement zone is intended to be a geometric space that only approximates the sample that is placed into the electric field between the electrodes (Bard Decl., ¶ 35), or is more strictly drawn to correspond precisely to the sample placed in this electric field during measurement (Bard Decl. ¶ 76 and Exh. 3 at 7-9). Dr. Bard further testifies that the measurement zone in the BD test strip contacts the surface of both electrodes. (Bard Decl. ¶ 52 & Exh. 3 at 7-9.)

BD/Nova attacks the sufficiency of Dr. Bard’s testimony in nearly identical ways as does Roche. For the same reasons discussed above, the Court finds that Dr. Bard offers competent testimony that even if the contours of the measurement zone are drawn to precisely include exactly the sample in the sample chamber that is in the electric field, the Aviva test strip would still contain a measurement zone meeting the requirements of the ‘745 claims, including being adjacent to the

1 working electrode and the counterelectrode. (Bard Decl. ¶ 52 & Exh. 3 at 7-9.) Dr. Bard's
 2 testimony provides a basis on which a reasonable jury could conclude there is a measurement zone
 3 in the Aviva test strip that satisfies the '745 claim requirements, and his testimony is not rendered
 4 insufficient merely because he cannot identify the precise contours of the measurement zone in all
 5 dimensions.

6 BD/Nova's expert, Dr. Wilson, opines that the measurement zone in the BD test strip is not
 7 adjacent to the counterelectrode based on his analysis that the only portion of the sample that is
 8 "interrogated" in the BD test strip is the sample to which the mediator can diffuse from the working
 9 electrode before the measurement is completed. (Wilson Decl., ¶¶ 9-18.) But just as with Roche,
 10 the conflicting expert testimony creates a triable issue of fact as to whether the sample that is
 11 "interrogated" in the BD test strip includes only that sample that encounters the diffusing mediator,
 12 or includes the sample that is located in the electric field between the electrodes during
 13 measurement. Similarly, Dr. Bard's testimony specifically critiquing a diffusion model as being
 14 inconsistent with the discussion of the measurement zone in the '745 specification (Bard Decl., ¶¶
 15 36-48) applies with equal force to several of Dr. Wilson's underlying assumptions, and a reasonable
 16 jury could rely on Dr. Bard's testimony to reject some or all of Dr. Wilson's ultimate opinions of
 17 non-infringement.

18 Accordingly, the Court finds that, on this record and using the parties' agreed-upon
 19 construction, there is a triable issue of fact as to whether the BD strip has a measurement zone
 20 that is adjacent to the working electrode and the counterelectrode.¹⁷

21 **C. The "reference counterelectrode" limitation of the '551 patent.**

22 BD/Nova contends that the BD test strip does not have a "reference counterelectrode" as
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26 ¹⁷ BD/Nova characterizes the dispute raised by its motion as "purely one of claim construction" regarding the
 27 measurement zone limitation. (Reply at 4:13-14.) However, the parties have already stipulated to a construction of
 28 "measurement zone." At oral argument, at the Court's request, the parties discussed whether this claim term might benefit
 from further construction by the Court in light of the conflicting views of the parties' experts. However, neither side has
 requested that the Court revisit or refine the construction, and the Court declines to do so *sua sponte* at the summary judgment
 stage.

1 required by the asserted ‘551 claims (claims 1-4) and as construed by this Court,¹⁸ and therefore
2 cannot infringe the ‘551 patent. BD/Nova raises two independent arguments in support of this
3 contention.

4 **1. Known potential relative to a standard.**

5 First, BD/Nova asserts that the counterelectrode in the BD test strip does not have a potential
6 that is “known . . . relative to a standard.” As with Bayer, Abbott concedes that the counterelectrode
7 in the BD test strip is a pseudoelectrode, and that its potential varies significantly depending on the
8 concentration of glucose in the sample. (Opp. at 9:15.) Once again, Abbott advances testimony by
9 its expert, Dr. Johnson, that the potentials can nonetheless be calculated for a given glucose level
10 based on assumptions about the accused products, and those calculations can be confirmed by
11 experimentally-measured potentials. (Johnson Decl., ¶¶ 22-23.)

12 Abbott’s literal infringement arguments against BD/Nova fail for the same reasons as against
13 Bayer. A pseudoreference, having a range of potentials that can be estimated through calculation
14 and confirmed by experiment, does not have “a known potential relative to a standard.” Moreover,
15 Abbott concedes pseudoreferences fall outside the literal scope of the Court’s construction.¹⁹
16 Accordingly, summary judgment of no literal infringement is appropriate.

17 **2. Insignificant variation in potential during measurement.**

18 Second, BD/Nova asserts that the potential of the BD test strip’s counterelectrode varies by
19 too much during the measurement to literally meet the claim construction’s requirement that it
20 “maintains its potential with only insignificant variation during the measurement.” BD/Nova cites to
21 Abbott’s expert’s own experiments which indicate that the potential varied by 40mV (drifting from
22 .31V to .27V) during the measurement. (Dahiya Decl., Exh. 19 at 8.) BD/Nova also cites to its own
23 expert’s experiments which found an even larger variation, from as much as 59mV to 87mV

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25 ¹⁸ For the same reasons discussed above in connection with Bayer, the Court declines to revise its construction of
26 this claim limitation.

27 ¹⁹ Abbott’s citations to various BD/Nova documents and witnesses that refer to the counterelectrode in the accused
28 product as a “reference electrode” or as placed in a “reference electrode well” (Hutcheson Decl., Exhs. 13, 14, 15, 16, 17,
18; Young Depo. at 125-137, Hutcheon Decl., Exh. 12; Winarta Depo. at 30-31, 43-57, Hutcheson Decl., Exh. 20) place an
excessive focus on talismanic language and do not raise a triable issue of fact in light of Abbott’s concession that the BD test
strip’s counterelectrode is a pseudoreference.

1 depending on glucose concentration. (Wilson Decl., ¶ 24 & Exh. 8.) Abbott does not dispute these
 2 quantitative results. BD/Nova's expert, Dr. Wilson, testified that this degree of variation cannot be
 3 considered insignificant for a counterelectrode. (Wilson Decl., ¶ 24.) Dr. Johnson, Abbott's expert,
 4 also acknowledged at deposition that a variation larger than 10mV was significant for a
 5 counterelectrode. (Johnson Depo. at 73-74, Supp. Dahiya Decl., Exh. 32.) Similarly, Dr. Hill, the
 6 named inventor on the '551 patent, testified that a variation of more than 20mV would be a
 7 significant variation. (Hill Depo. at 97:17-23.)

8 Against this backdrop, Abbott's evidentiary showing is insufficient to even meet its *prima*
 9 *facie* burden of demonstrating that the counterelectrode in the BD test strip maintains its potential
 10 with only insignificant variation during the measurement. First, Abbott argues that the variations are
 11 insignificant for a counterelectrode because the sensors are designed to function properly despite this
 12 variation in potential, but this response is untethered to the actual claim construction at issue and
 13 would improperly permit any working counterelectrode to meet this aspect of the "reference
 14 counterelectrode" claim construction. Second, Dr. Johnson's own testimony does not provide any
 15 reasoned basis for concluding that the 40mV variation is insignificant other than this faulty
 16 hypothesis. (Johnson Decl., ¶¶ 28-30, 51-52.) His comparison of the drift in the BD test strip with a
 17 commercial Abbott Precision Xtra strip is not a sufficient basis for a jury to conclude the drift in the
 18 BD test strip was insignificant. Dr. Johnson's tests showed a steady drift in the BD test strip
 19 (Johnson Decl., Exh. 7), where as Abbott's Precision Xtra strip showed little variation in potential
 20 other than initial instability as the sample first arrived. (Johnson Decl., Exh. 6.)

21 On this record, no reasonable jury could find that the at least 40mV variation in potential for
 22 the counterelectrode in the BD test strip was insignificant during the measurement period.²⁰ This
 23 provide a second basis for concluding there is no literal infringement of the '551 patent by the BD
 24 test strip.

25 3. Doctrine of equivalents.

26 Given that Dr. Johnson's testimony raises a triable issue of fact as to whether the BD test

27
 28 ²⁰ Contrary to Abbott's view articulated at oral argument, the portion of the '551 specification mentioning that the invention should be operated between +50 mV to +200 mV ('551 Patent at 7:25-28) does not suggest that the potential actually varies, by this amount or by any amount, during the measurement period.

1 strip counterelectrode is a pseudoreference (Johnson Decl. ¶ 25), the same evidence discussed above
 2 in connection with Bayer's noninfringement motion, showing a pseudoreference counterelectrode
 3 has known interchangeability with a reference counterelectrode, creates a triable issue of fact as to
 4 infringement by equivalents.

5 Accordingly, there is a triable issue of fact as to whether there is infringement by equivalents
 6 of the '551 patent by the BD test strip.

7 **D. Filter limitation of the '551 patent.**

8 BD/Nova contends that there is no infringement of the '551 patent by the BD test strip
 9 because the BD test strip has a chemical barrier that prevents red blood cells from contacting the
 10 conductive portion of the working electrode.

11 The Court construed the claim term "wherein said active electrode is configured to be
 12 exposed to said whole blood sample without an intervening membrane or other whole blood filtering
 13 member" to mean "the active electrode is exposed to whole blood during measurement and no part
 14 of the active electrode is prevented from being exposed to the whole blood sample through use of an
 15 intervening membrane or any other component that filters whole blood."

16 It is undisputed that the BD test strips contain a chemical barrier that increases the viscosity
 17 of the chemistry layer on top of the gold electrode. However, Abbott contends that a factual dispute
 18 exists as to whether red blood cells contact the working electrode during the measurement despite
 19 this layer. Abbott points to the testimony of its expert, Dr. Johnson, which describes experiments in
 20 which there was a large variation in blood glucose readings for the same glucose level when
 21 different levels of red blood cells were present. (Johnson Decl., ¶¶ 71-75.) Based on those
 22 experiments, Dr. Johnson opines that it is more likely that not that the BD test strip does not prevent
 23 red blood cells from reaching the electrode. (*Id.*)

24 BD/Nova attacks Dr. Johnson's testimony, pointing out that Dr. Johnson conceded in
 25 deposition that the observed "hematocrit" effect did not "necessarily" mean the red blood cells
 26 reached the electrode, because other factors could cause the hematocrit effect. (Johnson Depo. at
 27 140:6-141:4, Dahiya Decl., Exh. 18.) For example, Dr. Johnson conceded that oxygen or volume
 28 effects could also contribute to an observed hematocrit effect. (*Id.* at 139:8-18, 140:6-9.) This

testimony, however, does not negate a jury's ability to reasonably rely on Dr. Johnson's testimony that the "most likely" explanation for the observed effect is that red blood cells touch the surface of the electrode in the BD test strip. (Johnson Decl., ¶ 72.) The conflict between the inferences that can be drawn from the results of Dr. Johnson's indirect tests, and the inferences that can be drawn from Dr. Wilson's observations using SEM images which found no traces of red blood cells on electrodes frozen at the end of the measurement period (Wilson Decl., ¶¶ 32, 35), leaves this Court with competing inferences that are in tension and that must be weighed by a factfinder. The mere fact that Dr. Johnson's test results may merely constitute indirect or circumstantial evidence of infringement does not permit this Court to resolve the competing inferences in favor of BD/Nova at summary judgment.

Because of the existence of a triable issue of fact, the Court need not resolve at this time the underlying legal dispute between the parties – whether a chemical filtering agent that slows down red blood cells enough to prevent them from reaching the electrode during the measurement qualifies as a "component that filters whole blood."

E. Additional alleged failures of proof.

BD/Nova raise three additional arguments²¹ that it concedes fall outside the scope of the restrictions on summary judgment motions that were negotiated by the parties and approved by this Court's August 13, 2007 Supplemental Case Management Scheduling Order. In light of this concession, the Court declines to consider these arguments at this time.

IV. BD/Nova's Motion For Summary Judgment Of Invalidity Of The '890 Patent.

BD/Nova seeks summary judgment of invalidity with respect to the asserted claims of the '890 patent. The claims of the '890 patent asserted against BD/Nova are independent claim 11 and its dependent claim 12. As noted above, BD/Nova must establish by "clear and convincing" evidence, on the basis of undisputed facts, that the patent is invalid. BD/Nova asserts two

²¹ In particular, BD/Nova contends that: (1) the BD test strip does not meet the requirement of the '551 patent claims that the "electrodes are so dimensioned and positioned that they can be simultaneously completely covered by a single drop of whole blood"; (2) Abbott has no evidence of direct infringement regarding the '164 patent because Plaintiffs have no proof that BD's customers meet the limitation of "creating an unassisted flow" when they obtain a blood sample by lancing their skin; and (3) Abbott has failed to adduce evidence of the culpable state of mind required for indirect infringement of the '164 and '765 patents.

independent grounds for invalidity: (1) that the '890 patent is anticipated by the Nankai prior art patent, and (2) that the '890 patent is obvious in light of the Ikeda prior art patent in combination with the Nankai prior art patent.

A. The Nankai patent.

BD/Nova argues that the Nankai patent (Mehta Decl., Exh. 2) anticipates the '890 patent.

The Patent Act precludes the patenting of any invention that “was known or used by others in this country, or patented or described in a printed publication in this or a foreign country” before the date of its invention. 35 U.S.C. § 102(a); *see also Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1352 (Fed. Cir. 2003). Similarly, the Act provides that a patent claim is invalid if the patented invention is “described in a printed publication . . . more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102(b); *see also Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). To anticipate under either section 102(a) or section 102(b), a single prior art reference must disclose every limitation of the claimed invention. *See Schering*, 339 F.3d at 1377.²² If there is a disputed issue of material fact as to whether even a single element is disclosed in the prior art, summary judgment as to that patent claim must be denied. *See Rockwell Int’l Corp v. United States*, 147 F.3d 1358, 1363-64 (Fed. Cir. 1998).

Anticipation is a question of fact, *see SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005), and the determination of whether a prior art reference is enabling “is a question of law, although based upon underlying factual findings.” *Crown Operations Int’l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1376 (Fed. Cir. 2002). “However, without genuine factual disputes underlying the anticipation inquiry, the issue is ripe for judgment as a matter of law.” *SmithKline Beecham*, 403 F.3d at 1343. The burden of proof in all instances falls upon the party seeking to establish the invalidity of a patent claim, who “must overcome the presumption of validity in 35 U.S.C. § 282 by clear and convincing evidence.” *State Contracting & Eng’g Corp. v. Condotte Am., Inc.*, 346 F.3d 1057, 1067 (Fed. Cir. 2003).

²² Even where every limitation in the claim is not disclosed, a prior art may nevertheless anticipate the claimed invention if it inherently discloses a missing claim limitation. It must, however, be “clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

1 Here, to prove anticipation, BD/Nova must clearly and convincingly establish, using
2 undisputed facts, that every element of the asserted '890 patent claims is disclosed in the Nankai
3 patent.

4 **1. Figure 12.**

5 First, BD/Nova argues that Figure 12 of the Nankai patent discloses all of the elements of the
6 asserted '890 claims (claims 11 and 12). Abbott disputes that several '890 claim elements are
7 disclosed by Figure 12 of the Nankai patent.

8 **a. Directional flow.**

9 Abbott disputes that Figure 12 discloses a "elongated electrode support defining a sample
10 transfer path for directional flow of the same from an application point along said electrode
11 support", one of the claim limitations of the asserted '890 claims. This Court, in its claim
12 construction, has construed "sample transfer path" as the "route along which the sample moves", and
13 has construed "directional flow" as "the orientation and guidance in a particular direction."

14 The Court agrees with Abbott that, at a minimum, there is a disputed issue of fact as to
15 whether Figure 12 discloses a route along which the sample moves, such that the sample is provided
16 an orientation and guidance to move in a particular direction. The Nankai patent does not disclose
17 what direction the sample will flow, or what order the sample will fill the three fingers shown in
18 Figure 12. When the blood sample arrives at the first finger (channel #1), it is not guided in any
19 particular direction. The sample can continue straight or take a left turn down the first finger, or
20 both. (Heineman Decl., ¶ 16.) BD/Nova's fluid dynamics expert, Dr. Durgin, conceded this in
21 deposition. (Mehta Decl., Exh. 10 at 152:2-7; *see also* Hutcheson Decl., Ex. 11 at 81:24-82:8, 86:9-
22 15.) The mere fact that blood could, according to Dr. Durgin, be expected to flow into the first
23 channel before flowing into the second channel, and into the second channel before the third
24 channel, does not establish that Figure 12 orients or guides the sample in a particular direction.
25 BD/Nova's experts acknowledged in deposition that the path that the sample will take in the Figure
26 12 device cannot be determined by looking at the figure, and would have to be determined by
27 experiments or calculations. (Hutcheson Decl., Exh. 9 at 212:10-213:13; Exh. 11 at 86:16-89:1,
28 155:3-156:7.) Since Figure 12 allows such movement options, and does not disclose any defined

1 flow “in a particular direction”, BD/Nova has not demonstrated by clear and convincing evidence
 2 that Figure 12 provides “guidance in a particular direction” for the blood sample.

3 BD/Nova’s argument that the “particular direction” that the sample will be guided does not
 4 need to be predetermined (i.e., known before the sample is introduced) strains credulity. The claim
 5 language requires that the elongated electrode support “define” a route along which the sample
 6 moves with “orientation and guidance in a particular direction.” The support structure cannot define
 7 such a guided route in a particular direction if the direction of movement cannot be known before
 8 the sample is introduced. Moreover, even if BD/Nova were correct that the “particular direction”
 9 need not be known beforehand, as noted above there is considerable evidence that the blood sample
 10 does not even flow in a “particular direction” once introduced, but instead splits and flows in several
 11 different directions.

12 Because there is a disputed issue of fact as to whether the “directional flow” limitation is
 13 disclosed by Figure 12, Figure 12 does not anticipate claim 11 or 12 of the ‘890 patent.

14 **b. Downstream limitation.**

15 Abbott also disputes that Figure 12 discloses that the “reference or counter electrode [be]
 16 spaced downstream of said working electrode” (hereafter the “downstream limitation”). The Court
 17 agrees with Abbott that there is a disputed issue of material fact as to whether Figure 12 discloses a
 18 system in which the counterelectrode is “downstream” of the working electrode. Indeed, it is
 19 difficult to determine what would even correspond to “downstream” in the sample transfer path of
 20 Figure 12 given that Figure 12 does not appear to provide for flow of the sample in a single
 21 “particular direction.”

22 BD/Nova’s modified Figure 12, presented in its opening brief (Br. at 13), fails to rise to the
 23 level of a clear and convincing showing that Figure 12 discloses a counterelectrode that is
 24 “downstream” from the working electrode. The modified figure presented by BD/Nova has only a
 25 single working electrode and counterelectrode path. As an initial matter, BD/Nova asserts that Dr.
 26 Heineman (Abbott’s expert) conceded that such modifications would be evident to a person of skill
 27 in the art, and that the modifications contain all elements of claims 11 and 12, but the testimony
 28 cited by BD/Nova does not establish this. (Heineman Depo. at 129-30, Mehta Exh. 6.) More

1 fundamentally, the Nankai patent teaches that the multiple electrode system of Figure 12 was
 2 designed to provide increased accuracy (Hutcheson Decl., Exh. 12 at 8:31-45), and the other
 3 embodiments in the Nankai patent that include a single electrode system locate at least a portion of
 4 the counter electrode upstream of the working electrode (*id.* at Figs. 4, 6, 8 & 10). Against this
 5 backdrop, BD/Nova has not come forward with clear and convincing evidence that Nankai provides
 6 a teaching or suggestion to modify Figure 12 to include a one-electrode system.

7 Because BD/Nova has not shown, by clear and convincing proof, that the downstream
 8 limitation is disclosed by Figure 12, Figure 12 does not anticipate claim 11 or 12 of the '890
 9 patent.²³

10 **2. Figure 10.**

11 Second, BD/Nova argues that Figure 10 of the Nankai patent discloses all of the elements of
 12 the asserted '890 claims (claims 11 and 12). Abbott disputes that the downstream limitation of the
 13 '890 claims is disclosed by Figure 10 of the Nankai patent.

14 In BD/Nova's view, Figure 10 discloses the use of two separate counterelectrodes, 5 and 5'.
 15 Thus, BD/Nova argues, when sample is applied to introduction port 10, it flows across
 16 counterelectrode 5, then working electrode 4, and finally counterelectrode 5'. BD/Nova therefore
 17 argues that counterelectrode 5' is spaced downstream of working electrode 4 in the sample path.

18 However, the conclusion that Figure 10 discloses the use of two separate counterelectrodes
 19 is not undisputed on this record. "What a prior art reference discloses in an anticipation analysis is a
 20 factual determination." *Kim v. ConAgra Foods*, 465 F.3d 1312, 1325 (Fed. Cir. 2006). The
 21 specification of the Nankai patent does not directly discuss the issue, but Figure 10 shows the
 22 counterelectrode pieces 5 and 5' to be in electrical contact with each other and collectively connected
 23 to a single lead. (Mehta Decl., Exh. 2 at Fig. 10.) Moreover, Dr. Heineman, Abbott's expert, views
 24 this Figure as disclosing the use of a single counterelectrode exposed in two separate places
 25 (Heineman Decl., ¶ 28), an opinion that appears reasonable to the Court in light of the drawing itself.
 26 Dr. Turner, BD/Nova's expert, interprets Figure 10 differently (Mehta Decl., Exh. 7 at ¶ 6), but in

27
 28 ²³ Because BD/Nova has not established by clear and convincing proof that Figure 12 discloses the downstream
 limitation, combining the electrode configuration of Figure 12 with the test strip of Figure 8 would not anticipate the '890
 asserted claims, since BD/Nova does not assert that Figure 8 discloses the downstream element.

1 this situation the expert's conflicting interpretations of Figure 10 create a disputed issue of fact
2 regarding what is disclosed in the prior art reference.

3 The Court disagrees with BD/Nova that Figure 10 "plainly" shows that there are two separate
4 counterelectrodes such that Dr. Heineman's testimony can be disregarded. If anything, in the
5 absence of expert testimony, Figure 10 on its own appears to depict an electrical connection between
6 the two pieces 5 and 5' that suggests they operate as a single counterelectrode. Moreover, the patent
7 appears to refer to 5 and 5' as counterelectrode in the singular: "By drying with heating, the
8 electrode system comprised of an electrode for measurement 4 and a counter electrode 5 (5') is
9 formed." (Mehta Decl., Exh. 2 at 4:55-57.)²⁴

10 Accordingly, the Court finds BD/Nova has not carried its burden of "clearly and
11 convincingly" establishing, with undisputed facts, that Figure 10 discloses two separate
12 counterelectrodes. This precludes a finding that Figure 10 discloses the downstream limitation
13 element. If pieces 5 and 5' are the same counterelectrode, then the counterelectrode disclosed in
14 Figure 10 is not "downstream" from the working electrode since the blood sample encounters the
15 counterelectrode at piece 5 before the working electrode 4. Accordingly, the disputed state of the
16 record regarding what is disclosed in Figure 10 precludes a finding of invalidity based on the Figure
17 10 disclosure at the summary judgment stage.

18 The Court finds Abbott has failed to carry its burden of proof to establish that the Nankai
19 reference anticipates the asserted claims (claims 11 and 12) of the '890 patent.

20 **B. The Ikeda patent.**

21 BD/Nova contends that the asserted claims of the '890 patent are obvious in light of the
22 Ikeda patent, either alone or in combination with the Nankai prior art patent. Abbott does not
23 dispute the Ikeda patent discloses all of the elements of the claims 11 and 12 of the '890 patent; at
24 deposition, Abbott's expert, Dr. Heineman, conceded as much. (Heineman Depo. at 154-56, De
25 Decl., Exh. 1.)

26
27 ²⁴ The drafters of the Nankai patent also used the same kind of "prime" notation to denote two parts of a single
28 component, the spacer, in Figure 10: "Furthermore, as shown in the perspective view of the disassembled sensor in FIG. 10,
the spacer may be divided into two parts of 7 and 7' and the parts may be used as the spacer 8 . . ." (Mehta Decl., Exh. 2
at 7:56-60.)

1 However, Abbott does dispute whether the Ikeda patent qualifies as prior art. It is
2 undisputed that the Ikeda patent claims priority to a Japanese application filed on March 17, 1995.
3 Abbott contends that the invention claimed in the '890 patent was reduced to practice in the United
4 States before the March 17, 1995 filing date of the Ikeda patent, and that the Ikeda patent is therefore
5 not prior art that can invalidate a patent under 35 U.S.C. § 102(e).

6 **1. Burden of proof.**

7 As the party challenging the validity of a patent based on a document published before the
8 patentee's application, BD/Nova "[bears] the burden of persuasion by clear and convincing evidence
9 on all issues relating to the status of [the document] as prior art." *Mahurkar v. C.R. Bard, Inc.*, 79
10 F.3d 1572, 1576 (Fed. Cir. 1996) (analyzing Section 102(a) publication prior art). BD/Nova
11 incorrectly argues that because there is no dispute about the substance of Ikeda's invalidating
12 disclosure, the burden shifts to Abbott to show that Ikeda is not prior art. This is not the law.
13 Although the burden of production shifts to Abbott to come forward with evidence establishing its
14 invention date, once this burden is satisfied, the ultimate burden of persuasion that the Ikeda
15 application predated the '890 invention date remains on BD/Nova, and must be established by clear
16 and convincing evidence. *See id.* at 1578.²⁵ At the summary judgment stage, assuming Abbott
17 meets its burden of production, BD/Nova must prove by undisputed facts that the Ikeda patent
18 application was filed "before the invention" by Abbott of the claimed invention in the '890 patent.
19 32 U.S.C. § 102(e) (1998) (applicable to applications filed before November 2000).

20 **2. Prior invention.**

21 Abbott has met its burden of producing evidence that the '890 invention was embodied in
22 tangible form in the United States no later than November 1994, well before the March 17, 1995

23
24 ²⁵ *Apotex USA, Inc. v. Merk & Co.*, 254 F.3d 1031, 1037-38 (Fed. Cir. 2001), cited by BD/Nova, does not directly
25 speak to the allocation of burdens here. *Apotex* applied certain burden-shifting rules where an accused infringer asserted prior
26 invention under 35 U.S.C. § 102(g), a different defense than the anticipation/obviousness defense asserted here by BD/Nova.
27 Under *Apotex*, where the challenger of a patent has proven by clear and convincing evidence that "the invention was made
28 in this country by another inventor," 35 U.S.C. § 102(g), the burden of production shifts to the patentee to produce evidence
29 sufficient to create a genuine issue of material fact as to whether the prior inventor has suppressed or concealed the invention,
30 although the ultimate burden of persuasion remains with the party challenging the validity of the patent. *See id.* at 1037-38.
31 An anticipation/obviousness defense such as that asserted by BD/Nova here is distinct from a "prior invention" defense,
32 codified in 35 U.S.C. § 102(g)(2), that invalidates a patent if, before the patentee's invention, the same invention is "made
33 in this country by another who had not abandoned, suppressed, or concealed it." (Emphasis added.) A "prior invention"
34 defense premised on 35 U.S.C. § 102(g)(2) is not at issue here.

1 date to which the Ikeda patent claims priority. The evidence submitted by Abbott indicates that
 2 conception of the invention initially took place in the United Kingdom. (Watkin Decl. ¶ 20; Scott
 3 Decl., ¶ 17.) The declarations of Dr. Watkin and Dr. Scott also provide competent evidence that the
 4 ‘890 invention was reduced to practice, somewhere in the world, no later than when the 510(k) FDA
 5 application was submitted in November 2004. (Watkin Decl. ¶¶ 15-24; Scott Decl., ¶¶ 12-21.)
 6 Although the evidence submitted by Abbott refers to some testing that took place in the United
 7 States (Watkin Decl., ¶¶ 17, 20, 22; Scott Decl., ¶¶ 14, 17, 19), Abbott’s evidence is too ambiguous
 8 to ascertain whether the original reduction to practice of the ‘890 invention occurred in the United
 9 States, or as a result of any testing conducted in the United States.

10 However, an initial reduction to practice outside the United States is not fatal to Abbott’s
 11 attempt to meet its burden of production. Even assuming that the ‘890 invention was first reduced to
 12 practice in the United Kingdom, Abbott can claim a priority date from the date that the invention
 13 was first embodied in tangible form, or successfully performed, in the United States. *See Scott v.*
 14 *Koyama*, 281 F.3d 1243, 1247 (Fed. Cir. 2002) (“Reduction to practice in the United States requires
 15 that the invention be embodied in tangible form in the United States, not simply reported.”).²⁶
 16 Although Abbott’s evidence that Dr. Watkin visited the United States to provide information about
 17 the invention to the United States research team (Watkin Decl., ¶ 23) does not satisfy this showing,
 18 the testimony that Abbott’s witnesses have provided regarding the clinical trials that were performed
 19 on the test strip in New Mexico, Texas and Massachusetts between August and October 1994 is
 20 sufficient evidence to meet Abbott’s burden of production that the ‘890 invention had been
 21 embodied in tangible form in the United States no later than November 1994, particularly given the
 22 nearly identical drawings in the 510(k) application and the ‘890 patent. (Scott Decl., ¶ 23 & Exh. 8;
 23 Watkin Decl., ¶ 27; Heineman Decl., ¶ 30.)²⁷

24
 25 ²⁶ In contrast, for an invention conceived outside the United States, the date of conception for purposes of priority
 26 for a United States patent is the date the invention is first reported to the inventor’s agent within the United States. *See Scott*,
 243 F.3d at 1247.

27 ²⁷ To the extent BD/Nova asserts that Abbott’s evidence of events occurring outside the United States is irrelevant
 28 to the Court’s inquiry into the date of the ‘890 invention, the Court disagrees. 35 U.S.C. § 104 prevents Abbott from relying
 on knowledge or use of the invention outside the United States to directly prove the date of invention, but such evidence is
 still admissible for other purposes, such as to verify the identity of the invention or the fact of a domestic reduction to

Against this backdrop, BD/Nova does not point to any undisputed evidence that clearly and convincingly establishes that the Ikeda filing date was earlier than the date of invention in the United States for the claimed '890 invention.

3. Corroboration requirement.

BD/Nova contends that Abbott's evidence, even if it meets Abbott's burden of production, does not satisfy the corroboration requirement imposed for proof of a prior invention. Generally speaking, uncorroborated inventor testimony made in the course of litigation is insufficient to establish invention. *See Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1371-73 (Fed. Cir. 1998). Here, however, Abbott has come forward with sufficient documentary evidence (Hutcheson Decl., Exhs. 17 & 18; Scott Decl., Exhs. 1, 4, 6-9) made contemporaneously with the inventive process. *See Sandt Tech, Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1351 (Fed. Cir. 2001). Although BD/Nova accurately points out that this documentary evidence does not independently demonstrate that the tests were performed in the United States, or that the 1994 clinical trials involved sensors that possessed every element of the asserted '890 claims, such a degree of corroboration is not required. "The law does not impose an impossible standard of 'independence' on corroborative evidence by requiring that every point of a reduction to practice be corroborated by evidence having a source totally independent of the inventor." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1171 (Fed. Cir. 2006). At this stage, where the Court must draw all reasonable inferences in favor of Abbott, the Court finds that the documentary evidence submitted by Abbott adequately meets the corroboration requirement.

4. Abandonment, suppression and concealment.

BD/Nova contends that Abbott cannot rely on an earlier invention date than its application filing date because it allegedly abandoned, suppressed and concealed the invention. BD/Nova bears the burden, at the summary judgment stage, of proving that Abbott abandoned, suppressed and

practice. *See Breuer v. DeMarinis*, 558 F.2d 22, 28 (C.C.P.A. 1977). While 35 U.S.C. § 104 does not let Abbott claim an invention date based on the date of reduction to practice in the United Kingdom, *see Scott*, 281 F.3d at 1247, Abbott can still claim a date of invention as of the date an invention first conceived and/or reduced to practice outside the United States was embodied in tangible form in the United States. Abbott's evidence meets its burden of production that this happened before March 17, 1995.

concealed its invention by clear and convincing evidence based on undisputed facts.²⁸

BD/Nova has not met this burden. Drawing all reasonable inferences in Abbott's favor from the chronology of refinement, clinical testing, commercialization, and foreign deployment that is established by the record submitted by Abbott (Scott Decl., ¶¶ 22-31; Watkin Decl., ¶¶ 28-33), the Court cannot conclude that it has been clearly and convincingly shown that Abbott abandoned its invention. Even if an inference of abandonment could reasonably be drawn from Abbott's delay in filing the '890 patent application, that inference is not the *only* reasonable inference that can be drawn. To the contrary, examining "the circumstances surrounding [Abbott's] delay and the reasonableness of that delay", *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1568 (Fed. Cir. 1996), a factfinder could reasonably infer that Abbott's delay was reasonable given the complexity of the subject matter at issue and the fact that Abbott engaged in significant steps towards perfecting the invention and commercializing the invention through much of this time period. *See Checkpoint Sys., Inc. v. U.S. Int'l Trade Com'n*, 54 F.3d 756, 762 (Fed. Cir. 1995). The question of abandonment therefore cannot be resolved at the summary judgment stage.

Accordingly, there is a triable issue of fact as to whether the Ikeda patent renders the asserted '890 claims obvious, either alone or in combination with the Nankai prior art patent.

V. Defendants' Motion For Summary Judgment Of Invalidity Of The '745 Patent.

Defendants seek summary judgment of invalidity with respect to the '745 patent.²⁹ Defendants must establish by "clear and convincing" evidence, on the basis of undisputed facts, that each asserted '745 patent claim is invalid. Each asserted claim of the '745 patent is analyzed separately for purposes of invalidity.

Defendants assert six separate invalidity arguments: (1) that the Gotoh patent anticipates

²⁸ In this Court's view, because a valid patent has already issued to Abbott, 35 U.S.C. § 102(c) provides the legal framework under which BD/Nova's abandonment contention must be analyzed. 35 U.S.C. 102(c) provides a statutory basis for invalidating a patent where the applicant "has abandoned the invention." The cases cited by BD/Nova – *Paulik v. Rizkalla*, 760 F.2d 1270 (Fed. Cir. 1985), *Lutzker v. Plet*, 843 F.2d 1364 (Fed. Cir. 1988), and *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996) – all deal with interference proceedings in which no patent had yet been awarded, and where the issue of prior invention was determined under the standards of 35 U.S.C. § 105(g)(2), which allow the earlier inventor among two to prevail if that earlier inventor has not "abandoned, suppressed, or concealed" their earlier invention. As noted above, 35 U.S.C. § 105(g)(2) is not applicable here. Also, unlike here, no presumption of validity is afforded to the alleged first inventor in an interference proceeding.

²⁹ Bayer and Roche filed the motion, and BD/Nova filed a joinder in the motion.

claim 28 of the '745 patent, (2) that claim 28 of the '745 patent is invalidated by the CSL strip as a prior invention under 35 U.S.C. § 102(g), (3) that the Heller '225 reference anticipates all asserted '745 claims except claim 11; (4) that the asserted '745 claims are obvious as a matter of law, (5) that all asserted '745 claims are invalid because the term "measurement zone" is indefinite, and (6) that the specification does not enable the full scope of the asserted '745 claims.

A. The Gotoh patent.

Defendants contend that the Gotoh patent, U.S. Patent No. 6,071,391, invalidates claim 28 of the '745 patent. Abbott does not dispute the Gotoh patent is prior art.

1. Measurement zone less than 1 microliter.

Abbott disputes that the Gotoh patent discloses a measurement zone of less than 1 microliter. The Gotoh patent does not use the term measurement zone nor otherwise indicate which portion of the sample is to be interrogated during the analyte assay. Therefore, Defendants must rely on an inherency argument due to a lack of an explicit disclosure.

A disclosure is inherent only if the prior art necessarily functions in accordance with, or includes, the claim limitation. *See MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). The mere possibility that a claim element may be present in the prior art is not sufficient to establish inherency. *See id.* Inherency must be proven by clear and convincing evidence. *See In Re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002).

Here, there is a disputed issue of fact as to whether examples B1 and D1 operate with a sample chamber size of less than one microliter. The Gotoh reference does not describe the physical dimensions of the sample chamber or electrodes. The Gotoh reference merely discloses that a 1 microliter glucose solution is applied to the strip. However, the Gotoh reference does not indicate whether the sample chamber is completely filled. The testimony of Abbott's expert, Dr. Bard, creates a triable issue as to whether glucose sensors such as the Gotoh reference may operate accurately without the sample chamber being completely filled. (Bard Decl., ¶ 68; Bard Depo. at 399:19-402:3, 405:10-414:7, Hutcheson Decl., Exh. 5.)

Defendants' argument that the measurement zone must be smaller than one microliter, merely because the total solution applied to the strip to allow it to operate is one microliter, relies on

1 a flawed application of the “measurement zone” concept as defined in the ‘745 patent. The
2 stipulated construction of “measurement zone”, based on an explicit definition provided in the ‘745
3 patent, is that the measurement zone is “a region of the sample chamber sized to contain only that
4 portion of the sample that is to be interrogated during an analyte assay.” This definition certainly
5 requires the measurement zone to be no larger than the sample chamber, since it is a “region of the
6 sample chamber.” Defendants go a step further, and contend that the ‘745 patent’s definition of
7 measurement zone indicates that, in any given device, it can never be larger than the total amount of
8 blood in the strip. The Court disagrees. Contrary to Defendants’ view, the ‘745 patent does not
9 define the measurement zone as a “portion” of the sample. Moreover, the use of the word “only” in
10 the definition of measurement zone does not require that the measurement zone be no larger than the
11 sample in the sample chamber that is being interrogated. Rather, the definition precludes the
12 measurement zone from including sample that is not “to be interrogated”, but does not preclude the
13 measurement zone from including portions of the sample chamber that do not include any sample at
14 all. As discussed above in connection with Roche’s noninfringement motion, that the measurement
15 zone can include portions of the sample chamber where there is no sample is made clear by the ‘745
16 specification, which indicates that the volume of the measurement zone is a pre-existing geometric
17 space that can be defined and known in advance, based on the physical structure of the device,
18 before any blood sample is applied. In other words, the measurement zone is a space that is pre-
19 existing, that can be “empty” before any sample enters the device, and that later can be (but is not
20 necessarily) filled by sample. Because Defendants have not proven by clear and convincing
21 evidence that the sample chamber in the Gotoh reference either is less than 1 microliter, or is entirely
22 filled by the blood sample, Defendants have failed to establish that the measurement zone in the
23 Gotoh reference is necessarily less than 1 microliter in volume.

24 Defendants point to various alleged concessions by Abbott and its expert, Dr. Bard, that the
25 measurement zone can be no larger than the volume of sample applied to a device, but all of these
26 alleged statements were made by Abbott in connection with infringement issues concerning accused
27 devices in which Abbott contends the blood sample is known to substantially fill the sample
28 chamber. (Jorjani Decl., Exhs. 8 at 8, 6 at 313:23-214:18, 2 at 250:1-4.) Abbott’s statements do not

1 categorically establish that a measurement zone in other devices, such as the Gotoh device, can
2 never be larger than the volume of sample applied to the device.

3 Accordingly, Defendants have failed to establish, by clear and convincing evidence based on
4 undisputed facts, that the Gotoh patent inherently (i.e, necessarily) operates with a measurement
5 zone of less than one microliter.

6 **2. Background signal limitation.**

7 Defendants' anticipation argument premised on the Gotoh patent fails for a second reason as
8 well. On this record, there is a disputed issue of fact as to whether the Gotoh patent discloses the
9 background signal limitation of claim 28.

10 Claim 28 of the '745 patent requires that the background signal generated by shuttling be less
11 than five times the signal generated by an average normal physiological amount of glucose (the
12 analyte). The Gotoh reference does not discuss the amount of background signal present in the
13 invention. Therefore, Defendants bear the burden of demonstrating that this element is inherently
14 disclosed by the Gotoh reference.

15 Defendants' expert, Dr. Turner, has testified as to calculations that he performed using the
16 $(D_m t)^{1/2}$ formula stated in the '745 patent. ('745 patent at 43:49-57.) Specifically, Dr. Turner applied
17 a formula set forth in the '745 specification to calculate that the mediator used in the Gotoh
18 reference, ferricyanide, would diffuse a shorter distance than the spacing between the electrodes in
19 the Gotoh reference. On that basis, Dr. Turner testifies that "background signal due to mediator
20 shutting does not occur in a strip configured as described in Example B1 of the Gotoh '391 Patent,
21 and therefore the ratio of background to analyte signal is necessarily less than 5." (Turner Decl., ¶
22 39.)

23 The Court finds that this evidence, on its own, falls short of clear and convincing proof that
24 the Gotoh reference inherently discloses a background signal due to shuttling that is less than five
25 times the signal of glucose. Although Defendants contend that the '745 patent teaches that there can
26 be no background signal where the spacing of the electrodes exceeds the distance derived from the
27 $(D_m t)^{1/2}$ formula, there is a triable issue of fact as to whether this is so. The relevant portion of the
28 '745 patent reads as follows:

In some amperometric or potentiometric embodiments, the redox mediator circulation is decreased by separating the working electrode from the counter or counter/reference electrode such that the distance through which the redox mediator would diffuse during the measurement period is no greater than, for example, the distance between the electrodes. A redox mediator can diffuse a distance equal to $(D_m t)^{1/2}$, where D_m is the effective diffusion coefficient for the medium between the electrodes and t is time. For a measurement time period of 30 seconds and a redox mediator with effective diffusion coefficient between 10^{-5} and 10^{-6} $\text{cm}^2/\text{second}$, the electrodes should be separate by at least 100 μm , preferably at least 200 μm , and even more preferably at least 400 μm .

(‘745 patent at 43:49-62; Jorjani Decl., Exh. 1.)

Nothing in this passage states, or even directly implies, that all background signal due to shuttling is eliminated where the spacing between electrodes exceeds the $(D_m t)^{1/2}$ calculation.

Defendants have not identified clear and convincing evidence from which a reasonable jury could conclude that this is so; Dr. Turner’s declaration simply assumes this to be case. (Turner Decl., ¶¶ 28-29.)

Moreover, the ‘745 specification’s recommendation that the electrodes be spaced “even more preferably at least 400 μm ” is inconsistent with Dr. Turner’s assumption that no shuttling can occur if the electrodes are spaced $(D_m t)^{1/2}$ apart. Under the assumed values provided in the passage quoted above (measurement period of 30 seconds, redox mediator with effective diffusion coefficient between 10^{-5} and 10^{-6} $\text{cm}^2/\text{second}$), the diffusion distance derived from the formula is between 54 and 173 μm .³⁰ There would be no apparent need for the ‘745 inventors to recommend “even more preferably” a spacing of 400 μm if 200 μm eliminated *all* shuttling. This inconsistency between Dr. Turner’s assumption and the content of the ‘745 specification is a further reason that Defendants’ evidence falls short of clear and convincing proof.

Finally, even if Defendants had come forward with a sufficient *prima facie* case that this element is inherently disclosed in the Gotoh patent, the Court finds that the testimony from Abbott’s expert regarding flawed assumptions in Dr. Turner’s calculations would create a triable issue of fact regarding whether all background signal due to shuttling is eliminated where the spacing between electrodes exceeds the $(D_m t)^{1/2}$ calculation. (Bard Decl., ¶ 69 & Exh. B.)

³⁰ Defendants conceded the accuracy of this calculation at oral argument.

1 Because the record creates a triable issue of fact as to whether at least two ‘745 claim
2 elements are disclosed in the Gotoh reference, summary judgment of anticipation on the basis of this
3 prior art reference is inappropriate.³¹

4 **B. The CSL Strip.**

5 Defendants assert that claim 28 of the ‘745 patent is invalid under 35 U.S.C. § 102(g)
6 because of a prior invention inside the United States. In particular, Defendants contend that CSL, a
7 UK company that develops and manufactures blood glucose test strips, brought a batch of test strips
8 that satisfy claim 28 to Bayer’s laboratories in Indiana where they were tested on April 28 and 29,
9 1998. Accordingly, Defendants contend that the method of the CSL strips was practiced in the
10 United States prior to Abbott’s asserted invention date of July 30, 1998.

11 The evidence adduced by Defendants concerning the CSL test strips depends heavily on the
12 testimony of James McCann, managing director of CSL. Defendants have not produced the actual
13 test strips allegedly provided to Bayer in April 1998. Instead, CSL has provided strips that Mr.
14 McCann has testified came from the same batch (batch 7J2210) that were brought to Bayer in 1998.
15 (McCann Depo. at 46:25-47:22, 50:6-25, 58:10-59:16; Hutcheson Decl., Exh. 9.) Mr. McCann
16 testified that he found “one small bottle of strips in my desk, together with a load of other strips, that
17 actually labeled as that batch”, and explained that he “tend[ed] to hoard particular batches of strips .
18 . . chiefly for showing to clients when they visit”, and that the vial “happened to be one of the
19 batches that I had kept.” (*Id.* at 50:12-18.) The testimony of Mr. McCann linking the CSL test
20 strips that he found (and that the parties have examined) to the CSL test strips used in April 1998 at
21 Bayer is therefore a critical part of Defendant’s contention of a prior invention under 35 U.S.C. §
22 102(g).

23 Abbott has adduced evidence that raises credibility issues regarding this linchpin testimony
24 of Mr. McCann; such credibility issues will require resolution by the jury. *See Anderson v. Liberty*
25 *Lobby, Inc.*, 477 U.S. 244, 255 (1986); *Rockwell Int’l Corp.*, 147 F.3d 1358, 1361 (Fed. Cir. 1998).
26 First, there is sufficient evidence from which a reasonable jury could infer bias. Mr. McCann has a

27
28 ³¹ In light of these two genuine issues of disputed fact, the Court does not reach the parties’ disagreement over whether the Gotoh reference discloses two other ‘745 claim elements: (1) a measurement zone adjacent to the working electrode and counterelectrode, and (2) the non-flowing limitation.

1 financial interest in the outcome of this litigation and an apparent interest in obtaining an
2 invalidation of the '745 patent, given that his company, CSL, sells strips that compete with Abbott in
3 the low volume blood glucose sensor market (McCann Depo. at 108:6-109:11, 126:24-127:1,
4 Hutcheson Decl., Exh. 9), and which Abbott contends infringe the '745 patent. Mr. McCann sided
5 with Bayer in this litigation enough to cooperate with Bayer's attorneys and to volunteer to take
6 detailed measurements of the CSL test strips in support of Bayer's litigation efforts, and he met with
7 Bayer's attorneys for at least 6 hours to prepare for his deposition. (McCann Depo. at 126:11-128:9,
8 Hutcheson Decl., Exh. 9.)

9 Second, at least one contemporaneous document contains information from which a
10 reasonable jury could infer, drawing all inferences in Abbott's favor, that the device sent by CSL to
11 Bayer did not have the same dimensions and volumes as the test strip that Mr. McCann provided and
12 that the parties' experts have had an opportunity to measure. That document, a September 16, 1998
13 letter from Mr. McCann, described results from "our first batch of 1 [microliter] glucose sensors.
14 These require sample volume of 0.9 microliter and are 'flooded' by a 1 [microliter] sample."
15 (Hutcheson Decl., Exh. 14.) Mr. McCann attached pictures of the new and old devices to the letter,
16 and admitted in deposition that the picture he labeled as the old 2 microliter device was the same
17 device that Bayer tested in April 1998. (McCann Depo. at 185:3-187:3, Hutcheson Decl., Exh. 9.)
18 Though Mr. McCann later testified the description of "sample volume" in the letter is a reference to
19 the blood drop size (McCann Depo. at 179:2-19, Jorjani Decl., Exh. 38), rather than the sample
20 chamber size, a reasonable jury could disbelieve this testimony if they found his testimony to be
21 non-credible because of bias or self-interest.

22 Because there is a triable issue of fact regarding the credibility of Mr. McCann's testimony
23 that the device that Mr. McCann provided during his deposition is identical to the device used at
24 Bayer in April 1998, summary judgment of invalidity with respect to the CSL strip is inappropriate.
25 Accordingly, the Court need not reach the other arguments that Abbott raises with respect to the
26 CSL test strip.

27 **C. The Heller '225 reference.**

28 Defendants contend that the Heller '225 reference anticipates all claims of the '745 patent

1 asserted against Roche except claim 11, under 35 U.S.C. § 102(a).³² Abbott does not dispute that
2 the Heller reference is prior art.

3 **1. Elements of the ‘745 patent claims disclosed in the ‘225 reference.**

4 Roche’s expert, Dr. Weber, analyzed every element of the ‘745 claims asserted against
5 Roche and, except for elements unique to claim 11, found them all present in the Heller ‘225
6 reference. (Weber Decl., Exh. 1 at 42-61 & attached claim chart.) Dr. Weber’s analysis explains in
7 detail where each element of the asserted ‘745 claims is found in the ‘225 reference. The Court,
8 having compared Dr. Weber’s detailed citation to the ‘225 reference with the content of the ‘225
9 reference itself, finds Dr. Weber’s testimony to be well-supported. The Court finds that Dr. Weber’s
10 testimony constitutes a *prima facie* showing, sufficient to meet the clear and convincing standard,
11 that except for claim 11, every element of the ‘745 claims asserted against Roche is present in the
12 Heller ‘225 reference.

13 Other than with respect to two elements (the diffusible redox mediator element and the non-
14 flowing limitation), Abbott makes no effort in its opposition brief to challenge Dr. Weber’s analysis
15 or conclusions that elements in the ‘745 claims asserted against Roche are disclosed in the ‘225
16 reference. Similarly, in his rebuttal expert report, Abbott’s expert, Dr. Bard, focused his attention
17 solely on the diffusible redox mediator element, but did not otherwise contest Dr. Weber’s
18 conclusion that other ‘745 claim elements are disclosed in the ‘225 reference. (Jorjani Decl., Exh. 7
19 at 24; *see also* Bard Depo. at 158:14-24, Jorjani Decl., Exh. 2.) Indeed, Dr. Bard acknowledged at
20 deposition that of the items he could identify that were inventive in the ‘745 patent but were not
21 already disclosed in the ‘225 reference, none of them were elements of the ‘745 claims asserted
22 against Roche. (Bard Depo. at 203:24-205:3, 207:18-208:23.) The Court therefore finds that, on
23 this record, Defendants have established by clear and convincing proof, on the basis of undisputed
24 evidence, that every element in claims 1-5, 8, 21-23, 28, 31 and 34 of the ‘745 patent, with the
25 possible exceptions of the diffusible redox mediator element and the non-flowing limitation, is
26 disclosed in the ‘225 reference.

28 ³² Abbott has asserted claims 1-5, 8, 11, 21-23, 28, 31 & 34 of the ‘745 patent against Roche. Abbott has asserted additional ‘745 claims against other Defendants.

Abbott does argue that the question of whether the ‘225 reference anticipates the ‘745 patent must go to a jury simply because the PTO Examiner previously considered the ‘225 reference in connection with issuance of both the ‘745 patent and its parent, U.S. Patent No. 6,338,790. (Hutcheson Decl., Exhs. 2 at p. 4 & 18.) The Court disagrees. The mere fact that the PTO Examiner had been cited the reference does not create a triable issue of fact on this record. Although deference to the Examiner’s expertise is appropriate, that deference is expressed in patent litigation as a presumption of validity that requires Defendants to prove anticipation by clear and convincing evidence. However, “the presumption is one of law, not fact, and does not constitute ‘evidence’ to be weighed against the challenger’s evidence.” *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1258-59 (Fed. Cir. 2004).³³

a. Diffusible redox mediator.

Abbott asserts that the ‘225 reference does not disclose the use of a diffusible redox mediator,³⁴ but the plain language of the reference belies this assertion. The ‘225 reference discloses:

More preferably, the redox mediators of the present invention are bound or otherwise immobilized on the working electrode 22 to prevent undesirable leaching of the mediator into the sample. A diffusing or leachable (i.e., releasable) redox mediator is not desirable when the working and counter electrodes are close together. . . .

³³ Moreover, Abbott’s submission of a small portion of the prosecution history of the ‘760 patent (Hutcheson Decl., Exh. 18), which is the parent to the ‘745 patent, creates an incomplete record from which this Court cannot determine how the Examiner ultimately responded to the patentee’s arguments concerning the Heller reference. The document that Abbott has provided appears to be an amendment submitted by the ‘760 patent applicant, and appears to indicate that the Heller reference, together with other references, had been previously cited by the Examiner as a basis for a Section 103 obviousness rejection. (Hutcheson Decl., Exh. 18 at TH0042833.) In the amendment, the applicant argued that “Heller does not teach the use of diffusible mediators”, but the document does not include the Examiner’s response nor indicate whether any claims were allowed based on the applicant’s argument. (*Id.*) In any event, the applicant’s argument was made in the context of a Section 103 obviousness rejection, where the fact that the ‘225 reference teaches away from the use of a diffusible mediator (although disclosing it) could have a significant impact upon the motivation to combine references. As discussed below, the fact that the ‘225 reference teaches away from diffusible mediators is irrelevant to the anticipation inquiry.

³⁴ The Court finds that Abbott is not judicially estopped from making this assertion. In the claim construction brief and Markman hearing slides to which Defendants cite (Docket No. 189-1 in Case No. 3:04-cv-02123-MJJ & Jorjani Decl., Exh. 24), Abbott did not take the position that diffusible mediators were disclosed in the ‘164 specification (which is identical to the ‘225 reference’s specification). Rather, Abbott took the position that claim 16 of the ‘164 patent could not be limited to an immobilized mediator because an immobilized mediator was simply a preferred embodiment. It does not necessarily follow from Abbott’s claim construction argument – essentially, the argument that the claims were not limited to a specific type of mediator – that the ‘164 specification disclosed the use of diffusible mediators or any specific type of mediator. Accordingly, imposition of judicial estoppel is not appropriate on this record.

1 (Jorjani Decl., Exh. 23 at 9:25-29.)

2 This is not the only disclosure of using a diffusible redox mediator in the ‘225 reference; the
3 reference also indicates that “[p]referably, there is little or no leaching of the redox mediator away
4 from the working electrode” and that “[i]n general, mediators suitable for use in the invention have
5 structures which prevent or substantially reduce the diffusional loss of redox species during the
6 period of time that the sample is being analyzed.” (Jorjani Decl., Exh. 23 at 9:22-24 & 10:25-27.)
7 Both passages acknowledge the possibility of using a leaching or diffusing mediator, although
8 clearly the drafters preferred those that did not leach or diffuse. Moreover, independent claim 127 in
9 the ‘225 reference calls for a “redox mediator on its working electrode” and its dependent claim 128
10 states that the redox mediator is a non-leachable mediator, implying under principles of claim
11 differentiation that the redox mediator in claim 127 includes leachable mediators. (*Id.* at 63.)

12 Thus, the ‘225 reference clearly discloses the use of a diffusible redox mediator as a means
13 of practicing the disclosed invention, even though the reference indicates that an immobilized (rather
14 than diffusible) redox mediator is the “preferred” or “desired” method of practicing the invention.
15 Dr. Weber, Roche’s expert, so testifies. (Weber Decl., Exh. 1 at 42-43 & attached claim chart.)
16 Abbott’s countervailing evidence fails to create a triable issue of fact on this point. In fact, the
17 expert put forward by Abbott regarding this invalidity question, Dr. Bard, concedes that the Heller
18 ‘225 reference discloses that diffusible mediators can be used, although they are not preferred.
19 (Bard Depo. at 141:23-25, 142:9-143:5, 158:14-24, Jorjani Decl., Exh. 2.)³⁵

20 With no support from its own expert, Abbott instead cites to testimony from an expert report
21 of Dr. Turner, an expert witness for co-defendant Bayer. However, Dr. Turner’s testimony does not
22 raise a triable issue of fact as to whether the use of a diffusible redox mediator is disclosed in the
23 ‘225 patent. Dr. Turner does not deny that the ‘225 reference discloses diffusible redox mediators,
24 but simply opines that the ‘225 reference “teach[es] one of ordinary skill in the art not to use
25 diffusible mediators” (Turner Depo. at 257:8-20, Hutcheson Decl., Exh. 16; *see also id.* at 263:3-
26

27
28 ³⁵ In his rebuttal expert report, Dr. Bard’s did not affirmatively assert that diffusible redox mediators were not disclosed in the ‘225 reference; instead, he merely opined that “reasonable minds can differ” about whether it is disclosed. (Jorjani Decl., Exh. 7 at 24.)

266:24; Hutcheson Decl., Corrected Exh. 15 at 16-17)³⁶ and “teaches a way [sic] from using diffusible mediators.” (Turner Depo. at 265:16-17, Hutcheson Decl., Exh. 16.) While Dr. Turner’s testimony supports Abbott’s view that the ‘225 reference “teaches away” from a diffusible mediator, it does not provide a basis upon which a reasonable jury could conclude that a diffusible mediator is not disclosed. A reference anticipates an invention even if, after disclosing the invention, the reference then disparages it. See *Upsher-Smith Labs., Inc. v. PamLab, L.L.C.*, 412 F.3d 1319, 1323 (Fed. Cir. 2005); *Celeritas Techs., Ltd. v. Rockwell Int’l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). “[T]he question whether a reference ‘teaches away’ from the invention is inapplicable to an anticipation analysis.” *Upsher-Smith*, 412 F.3d at 1323. In any event, even if Abbott could point to expert testimony that there is no disclosure of a diffusible redox mediator in the ‘225 reference (which it cannot), such expert testimony would be directly contrary to the plain language of the reference, and could not create a genuine issue of disputed fact.

b. Non-flowing limitation.

No disputed issue of fact exists as to whether the Heller ‘225 reference discloses the “non-flowing limitation” of the ‘745 patent. The Heller ‘225 reference explicitly states that “[t]he potential is preferably applied after the sample has come to rest in the sample chamber.” (Jorjani Decl., Exh. 23 at 24.) As this Court has previously determined in its claim construction order on the ‘164 patent (which has the same disclosure as the Heller ‘225 reference), “[a]s the [‘164] specification indicates, it is important to the proper functioning of the sensor that the sample be at least temporarily immobilized during measurement.” (Jorjani Decl., Exh. 11 at 15:23-25.) In support of its contention that the non-flowing limitation is not disclosed, Abbott points only to the testimony of Defendant’s expert, Dr. Durgin, regarding the need for experimentation to determine whether the BD test strip meets the non-flowing limitation for infringement purposes. (Durgin Depo at 110-11, Hutcheson Decl., Exh. 7.) This testimony does not create a triable issue of fact, because the non-flowing limitation is expressly disclosed in the Heller ‘225 reference, and there is thus no need to resort to an inherency argument.

³⁶ Abbott filed a corrected version of Exhibit 15 on January 14, 2008. The corrected Exhibit 15 (cited as “Corrected Exh. 15”) is the invalidity report that Dr. Turner prepared for BD/Nova. The original Exhibit 15, an expert report that Dr. Turner prepared on behalf of Bayer, is also in the record and is cited below as “Original Exh. 15.”

2. Enabling reference.

In the alternative, Abbott argues that even if the diffusible redox mediator element and non-flowing limitation are disclosed in the ‘225 reference, Dr. Turner’s deposition testimony and expert report create a triable issue of fact as to whether the ‘225 reference is enabling for purposes of an anticipation analysis. *See In re Paulson*, 30 F.3d 1475, 1479 (Fed. Cir. 1994) (“the reference must be enabling and describe the applicant’s claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention.”); *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991). The testimony that Abbott identifies (Turner Depo. at 260, Hutcheson Decl., Exh. 16) is grounded in Dr. Turner’s view that the ‘164 patent (which has the same disclosure as the ‘225 reference) “teaches away” from the use of a diffusible mediator, and against this backdrop, he opines that one could not make the invention if required to “us[e] the teachings of the ‘164 patent.” (*Id.*) Dr. Turner expressed a similar view in his expert report for BD/Nova. (Hutcheson Decl., Corrected Exh. 15 at p. 17.)³⁷ In context, this testimony simply does not speak to the relevant enablement question: whether one of ordinary skill could, using the information in the ‘164 patent, could construct a sensor with a diffusible mediator and a measurement zone smaller than a microliter.³⁸ However, Abbott’s own expert, Dr. Bard, does directly opine on the enablement question in his report, and entirely undercuts Abbott’s position by testifying that “[o]ne of ordinary skill in the art could make a sensor with diffusible mediators using the teachings of the ‘164 Patent whether the ‘164 Patent explicitly discloses them or not.” (Jorjani Decl., Exh. 7 at 24.) Based on this record, and the testimony of Abbott’s own expert, a reasonable jury would have to conclude that the ‘225 reference enables the asserted ‘745 claims.

At oral argument, Abbott also contended that a footnote in Defendants’ opening brief, which

³⁷ Dr. Turner’s view in his BD/Nova expert report that “the inventors of the ‘164 Patent did not possess a method of constructing an analyte sensor for determining the concentration of an analyte from 500 nL or less of a body fluid, except by using an immobilized sensor” (Hutcheson Decl., Corrected Exh. 15 at p. 17) does not create a triable issue as to whether the ‘225 reference enables the asserted ‘745 claims. This testimony does not directly speak to what one of ordinary skill in the art would be able to construct using the ‘164 disclosure. Even if it did, the ‘164 claim limitation with which Dr. Turner was concerned included a 500 nL limitation on body fluid not found in the asserted ‘745 claims.

³⁸ Indeed, in his expert report on behalf of Bayer, Dr. Turner expressed his view regarding enablement that does not support Abbott. Dr. Turner indicated that, in his opinion, the use of diffusing mediators in a small strip with electrodes spaced less than 1000 μm apart was obvious to one of ordinary skill in September 1998. (Hutcheson Decl., Original Exh. 15 at 60.)

1 states that “Dr. Weber concluded that claim 8 of the ‘745 patent is disclosed by the Heller ‘225
 2 reference but that the disclosure is not enabling” (Br. at 14 n.18), creates a triable issue of fact
 3 regarding enablement at least with respect to claims 8 and 11. However, upon reviewing Dr.
 4 Weber’s actual testimony, Defendants’ footnote itself appears to be an inaccurate summary of Dr.
 5 Weber’s testimony and opinions. Dr. Weber did not testify, anywhere in his declaration or expert
 6 report, that claim 8 of the ‘745 patent is not enabled by the disclosure of the use of amperometry in
 7 the ‘225 reference. Rather, Dr. Weber simply indicated that:

8 Though the [Heller ‘225] patent focuses on coulometry, it certainly
 9 mentions measurement by amperometry e.g., page 26, near line 13.
 10 However, the text of the ‘225 patent is very similar to that of the ‘745
 patent, and provides essentially no description of how one would build
 and use an amperometric system.

11 (Weber Decl., Exh. 1 at 56.) This testimony does not express any view as to whether a person with
 12 ordinary skill in the art would, using the ‘225 reference as a guide, be able to construct an
 13 amperometric sensor satisfying the requirements of claim 8 of the ‘745 patent. In this Court’s view,
 14 on such a record, an inaccurate footnote in Defendants’ own brief does not constitute the quantum of
 15 evidence sufficient to raise a triable issue of fact as to whether the ‘225 reference enables claims 8
 16 and 11, because no reasonable jury could conclude that the footnote accurately states Dr. Turner’s
 17 position.

18 Accordingly, the Court find that claims 1-5, 8, 21-23, 28, 31 & 34 of the ‘745 patent are
 19 anticipated by the Heller ‘225 reference.

D. Obviousness.

21 Defendants contend that the Gotoh patent, the CSL strip, and the Heller reference, in
 22 combination, render all claims of the ‘745 patent asserted against Roche obvious. Because the Court
 23 has found that claims 1-5, 8, 21-23, 28, 31 & 34 are anticipated by the Heller ‘225 reference, the sole
 24 asserted claim that must be analyzed for Section 103 obviousness is claim 11 of the ‘745 patent.
 25 However, given that there are disputed issues of fact as to whether the CSL strip can be considered
 26 prior art at all, the Court cannot consider the CSL strip as part of the available prior art for purposes
 27 of this Motion. Accordingly, the sole question before the Court at this stage is whether undisputed
 28 facts establish, by clear and convincing evidence, that the Heller ‘225 reference, in combination with

the Gotoh patent, renders claim 11 obvious.

To prove that a patented invention is invalid as obvious, the accused infringer must identify prior art references “which alone or combined with other references would have rendered the invention obvious to one of ordinary skill in the art at the time of invention.” *Al- Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citations omitted). “Obviousness is a question of law premised on underlying findings of fact.” *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1332 (Fed. Cir. 2005). These underlying factual determinations include: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and, if necessary, (4) secondary evidence of nonobviousness. *See Para-Ordnance Mfg., Inc. v. SGS Imps. Int’l, Inc.*, 73 F.3d 1085, 1087-88 (Fed. Cir. 1995). Like anticipation, the affirmative defense of obviousness must be established by clear and convincing evidence. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1353 (Fed.Cir. 2003).³⁹

Here, the Court concludes that Defendants have failed to meet their burden. Dr. Weber’s declaration and attached expert report (Weber Decl., Exh. 1 at 61-62) do not contain sufficient non-conclusory testimony on the subject of obviousness to permit a reasonable jury to conclude, by clear and convincing evidence, that one of ordinary skill in the art would combine the Heller and Gotoh references. This is particularly true where (as discussed above) the ‘225 reference undisputedly teaches away from the use of a diffusible redox mediator. Defendants’ evidentiary submission simply falls short of a *prima facie* showing that one of ordinary skill in the art would, despite the warnings against using diffusible mediators in the Heller ‘225 reference, have an apparent reason to combine the Heller reference with the diffusible mediator strips of Gotoh. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Dr. Weber’s brief discussion of obviousness is not directed specifically to the combination of these two specific references, and fails to rise to the level of clear and

³⁹ The Supreme Court has recently clarified the test for obviousness, specifically the analysis applicable to whether there exists some “teaching, suggestion or motivation” (“TSM”) to combine prior art references, which has traditionally been a requirement for a finding of obviousness. The Court described the TSM test as a “helpful insight” rather than a rigid formula, and held that “the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The Court further emphasized the need for courts to value “common sense” over “[r]igid preventative rules.” *Id.* at 1742-43.

1 convincing proof.

2 **E. Indefiniteness.**

3 Defendants contend that the claim term “measurement zone” is indefinite, rendering every
4 claim in the ‘745 patent invalid. Indefiniteness is an issue closely related to claim construction. In
5 determining whether the claim is sufficiently definite, the Court must analyze whether one skilled in
6 the art would understand the bounds of the claim when read in light of the specification. *See Allen*
7 *Eng’g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1348 (Fed. Cir. 2002). However, “[o]nly claims not
8 amenable to construction or insolubly ambiguous are indefinite.” *Halliburton Energy Services, Inc.*
9 *v. M-I LLC*, 514 F.3d 1244, 1250 (Fed. Cir. 2008) (quotations omitted). “If the meaning of the claim
10 is discernible, even though the task may be formidable and the conclusion may be one over which
11 reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on
12 indefiniteness grounds.” *Id.* at 1249.

13 Here, Defendants contend that the ‘745 claims are indefinite because a person of skill in the
14 art could not determine whether a co-planar, amperometric sensor, such as those accused of
15 infringement in this case, has a measurement zone as required by the patent claims. The Court finds
16 Defendants’ argument unavailing for several reasons. To begin with, the parties stipulated to a
17 construction of the “measurement zone” term, which cuts against any conclusion that the term is not
18 amenable to construction. The inventors of the patent, acting as their own lexicographers,
19 specifically defined the measurement zone as “a region of the sample chamber sized to contain only
20 that portion of the sample that is to be interrogated during an analyte assay.” (‘745 patent at 7:7-10.)
21 Although the parties’ experts have arrived at competing views over whether the accused Aviva and
22 BD test strips contain a measurement zone within the definition of the ‘745 patent, all three experts
23 (Drs. Weber, Wilson and Bard) premised their conclusions on their specific understanding of what a
24 measurement zone is as taught by the ‘745 patent. The mere fact that these experts, when applying
25 the claim term to the accused device, can reasonably disagree about the location and scope of the
26 measurement zone does not render the claim term indefinite. *See Halliburton*, 514 F.3d at 1249.

27 Moreover, the Court notes that the ‘745 patent provides not only an express definition of the
28 “measurement zone” claim term (which the parties have stipulated to for claim construction

purposes), but considerable additional information regarding how the measurement zone can be identified for various electrode configurations, which sheds light on the meaning of the phrase “portion of the sample that is to be interrogated” found in the inventors’ express definition. While those descriptions are not rigorously precise, they provide adequate guidance as to the shapes and contours of measurement zones for devices with either facing or co-planar electrodes.⁴⁰ *Cf. Xerox Corp. v. 3Com Corp.*, 458 F.3d 1310, 1323 (Fed. Cir. 2006) (“While those descriptions are not rigorously precise, they provide adequate guidance as to the types of symbols that are ‘well separated from each other in sloppiness space,’ particularly in light of the difficulty of articulating a more exact standard for the concept.”). This Court finds that because the inventors provided “a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine” whether the measurement zone limitation is satisfied by an accused device, the ‘745 claim terms are not indefinite. *In re Marosi*, 710 F.2d 799, 803 (Fed.Cir.1983).

F. Enablement.

Defendants contend that the ‘745 patent claims are not enabled because all of the patent’s claims cover co-planar amperometric devices, but the ‘745 specification does not disclose how to construct or measure a “measurement zone” in such a device.

The Court finds that, on the record before it, there is a triable issue of fact as to whether the ‘745 specification discloses how to construct a co-planar, amperometric device with a “measurement zone.” Dr. Bard’s testimony on this subject indicates that whether the measurement zone is intended to be a geometric space that only approximates the sample that is placed into the electric field between the electrodes, or is more strictly drawn to correspond precisely to the sample placed in this electric field during measurement, a person of ordinary skill in the art would be able to construct, without undue experimentation, a co-planar amperometric sensor with a measurement zone that

⁴⁰ For example, discussing a specific embodiment with co-planar electrodes, the specification provides information as to the size and location of the measurement zone. (‘745 Patent at 26:18-23, 26:59-27:5). It indicates that the “sample chamber 26 is in contact with both electrodes and is bounded on the side opposite the electrodes by a non-conducting inert base.” (*Id.* at 26:18-23.) It further indicates that in such a situation, the “sample chamber 26 is the space between the two electrodes 22, 24 and/or the inert base 30.” (*Id.* at 26:60-62.) The specification indicates that in this co-planar embodiment, “the measurement zone has a volume that is approximately equal to the volume of the sample chamber. In a preferred embodiment the measurement zone includes 80% of the sample chamber, 90% in a more preferred embodiment, and about 100% in a most preferred embodiment.” (*Id.* at 26:66-27:5.)

1 satisfies the '745 claims by keeping the total sample chamber size less than a microliter. (Bard Decl.,
 2 ¶¶ 56-57.) A reasonable jury could conclude, from Dr. Bard's overall testimony explaining the basis
 3 for his enablement opinion (Bard Decl., ¶¶ 11-29, 35), that the '745 specification would enable one
 4 of ordinary skill in the art to construct a co-planar, amperometric device within the scope of the
 5 claims.⁴¹ As discussed above in connection with Roche's and BD/Nova's non-infringement
 6 motions, there is of course conflicting testimony from Defendants' experts that creates a dispute of
 7 fact over whether building a device in this manner would indeed contain a measurement zone
 8 satisfying the '745 claims, but this factual dispute cannot be resolved at the summary judgment
 9 stage.

10 The Court also cannot accept Defendants' argument that the Court should reject Dr. Bard's
 11 explanation that one could ensure the measurement zone in a co-planar, amperometric device is less
 12 than a microliter by making the total capacity of the sample chamber less than one microliter. Dr.
 13 Bard's explanation does not, as Defendants argue, somehow "vitiate" the measurement zone claim
 14 element. The parties' stipulated construction of the measurement zone indicates that the
 15 measurement zone is a "region of the sample chamber." It is logical to infer from this construction,
 16 as Dr. Bard does, that if a device has a measurement zone, and if a device has a sample chamber of
 17 less than one microliter, the measurement zone is necessarily less than one microliter as well.
 18 Moreover, nothing in the parties' stipulated construction precludes the measurement zone from
 19 including the entirety of the sample chamber. Indeed, the '745 specification expressly indicates
 20 when discussing several specific embodiments that in "a most preferred embodiment" the
 21 measurement zone includes "about 100%" of the sample chamber. ('745 patent at 27:1-4.)

22 Nor is the Court persuaded that the '745 patent is not enabled merely because Dr. Bard
 23

24 ⁴¹ Defendants contend that in Figure 2, the only figure of the '745 patent discussing a co-planar electrode
 25 arrangement, "the sample chamber is erroneously described as being located in the 'space between' the electrodes, as it would
 26 be in a facing electrode configuration." (Mot. at 19:24-25.) This is itself an inaccurate characterization of the '745 patent,
 27 which states: "In the embodiment of the invention illustrated in FIGS. 1 and 2, sample chamber 26 is the space between the
 28 two electrodes 22, 24 *and/or the inert base 30*." ('745 patent at 26:60-62, emphasis added.) Defendants also, rather
 egregiously, overstate Dr. Bard's purported concession on this issue. Defendants characterized the '745 specification
 inaccurately when asking Dr. Bard about it (Bard Depo. at 65:13-16 & 65:24-66:3, Jorjani Decl., Exh. 2), rendering the
 meaning of his response ("I see it, but I don't agree with it", *id.* at 66:4) ambiguous. Moreover, Dr. Bard interrupted the next
 question to retract his answer: "Wait, no, no, let me – let me look at this again. I'm sorry. Let me look carefully at Figure
 2. I'm sorry. I have to go back and see what some of these elements are." (*Id.* at 66:5-10.)

1 testified that, to determine whether the measurement zone was less than a microliter in a device with
 2 a 1.25 micoliter sample chamber, he would have to perform a complicated finite element analysis.
 3 (Bard Depo. at 312:19-313:19, Jorjani Decl., Exh. 41.) Dr. Bard has testified that such a calculation
 4 is within the capability of one of ordinary skill in the art. (Bard Decl., ¶ 32.) In any event, the test
 5 for enablement is whether one of ordinary skill in the art could practice the full scope of the claims
 6 without undue experimentation, not whether one of ordinary skill of the art could easily assess
 7 whether a given co-planar amperometric device has a measurement zone satisfying the claims.

8 Because there is a triable issue of fact as to whether the ‘745 patent is enabled, summary
 9 judgment of invalidity is not appropriate on this ground.

10 **G. Reconsideration of the construction of the “background signal” limitation.**

11 For reasons similar to Abbott’s request to reconsider the “reference counterelectrode”
 12 limitation, the Court declines Abbott’s request to reconsider its construction of the “background
 13 signal” limitation. The Court based its current construction on intrinsic evidence, and the disfavored
 14 extrinsic evidence submitted by Abbott is not a sufficient basis to alter the construction. In its April
 15 27, 2007 claim construction order, the Court based its construction largely on the premise that, given
 16 the specific content of the ‘745 specification, this claim limitation was intended as a performance
 17 characteristic that is measured by the formulas described in the specification. Although Abbott
 18 submits deposition testimony addressing how the concept of “background signal” is generally
 19 understood by numerous Defendant witnesses (*see* evidence cited at page 24 of Abbott’s
 20 Opposition), Abbott has not persuaded the Court that such evidence should cause the Court to depart
 21 from the specific construction suggested by the discussion of this claim limitation in the ‘745
 22 specification.⁴²

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28 ⁴² Abbott has also not established that these witnesses were using the term “background signal” consistent with how one skilled in the art would have used the term at the time the ‘745 application was filed.


CONCLUSION

For the foregoing reasons, the Court rules as follows:

- (1) The Court **GRANTS IN PART AND DENIES IN PART** Bayer's motion for summary judgment of noninfringement concerning the '551 patent. Summary judgment of no literal infringement is appropriate as to Bayer's Microfill and Autodisc strips with respect to all claims of the '551 patent asserted against Bayer (claims 1-4). However, the Court denies summary judgment with respect to infringement of the '551 patent by these strips under the doctrine of equivalents.
 - (2) The Court **DENIES** Roche's motion for partial summary judgment of noninfringement concerning the '745 patent.
 - (3) The Court **GRANTS IN PART AND DENIES IN PART** BD/Nova's motion for summary judgment of noninfringement. Summary judgment of noninfringement is appropriate as to the BD test strips with respect to all claims of the '164 patent asserted against BD/Nova (claims 16, 20, 22, 23, 26, 27, 34, 36-38 and 40) and all claims of the '745 patent asserted against BD/Nova (claims 1, 3-5, 8, 11, 21-23, 26-30, 34, 37 and 38). Summary judgment of no literal infringement is also appropriate as with respect to all claims of the '551 patent asserted against BD/Nova (claims 1-4). However, the Court denies summary judgment with respect to infringement of the '551 patent by the BD test strip under the doctrine of equivalents.
 - (4) The Court **DENIES** BD/Nova's motion for summary judgment of invalidity concerning the '890 patent.
 - (5) The Court **GRANTS IN PART AND DENIES IN PART** Defendants' motion for summary judgment of invalidity concerning the '745 patent. The Court finds claims 1-5, 8, 21-23, 28, 31 & 34 of the '745 patent to be anticipated and therefore invalid.
- In all other respects, the Court denies this motion.

IT IS SO ORDERED.

Dated: April 3, 2008


MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE